AP/FC

This Appeals Brief as required by 37CFR 41.37 is in response to the Final Office dated May 5 2008.

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Real Party of Interest:

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Group Art Unit: 3761

Examiner : Leslie Deak

Title: HYBRID ARTERIOVENOUS SHUNT

Attorney Docket: 1800-000001

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I. Related Appeals and Interferences.

There are no appeals or interferences

II. STATUS OF CLAIMS

These are the claims that are involved in the appeal

1. (amended, appealed) An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, said lead end

being configured for subcutaneous connection to an artery by anastomosis, wherein said

arterial graft has a first diameter; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end,

said depositing end being configured for insertion through a vein into the right atrium of

the heart, wherein said venous outflow catheter has a second diameter different from said

first diameter; and

c. a cylindrical cuff operable to direct passage of blood from said arterial graft to said

venous outflow catheter, said cuff comprising an inlet in blood communication with

an outlet:

i. said inlet being disposed about and connected to said terminal end of said

arterial graft; and

ii. said outlet being disposed about and connected to said intake end of said

venous outflow catheter; wherein said cuff provides a secure fit for

said arterial graft first diameter and said venous outflow catheter second diameter.

2. (previously presented, appealed) The arteriovenous shunt of claim 1 wherein said arterial graft

is made of a biocompatible flexible material.

3. (amended, appealed) The arteriovenous shunt of claim 2, wherein said biocompatible

flexible material is polytetrafluoroethylene(PTFE) or other biocompatible material

4. (appealed) The arteriovenous shunt of claim 1, wherein said arterial graft has a

diameter from about 2 mm to about 8 mm and a length from about 20 cm to about 60 cm.

5. (appealed) The arteriovenous shunt of claim 4, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length of about 40 cm.

6. (appealed) The arteriovenous shunt of claim 1, wherein said artery is the brachial,

axillary, femoral or external iliac artery.

7. (Appealed) The arteriovenous shunt of claim 1, wherein said cuff is

polytetrafluoroethylene or polyethylene terephthalate.

8. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 1 mm to about 7 mm and a length of from about 20 cm to about 80 cm.

9. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 5 mm to about 7 mm and a length of from about 40 cm to about 60 cm.

10. (amended, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of other biocompatible materials.

11. (appealed) The arteriovenous shunt of claim 1, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

12. (previously presented, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

13. (amended, appealed) A system for performing hemodialysis on a patient comprising: a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet with blood communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said subcutaneous graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter;

14. (previously presented, appealed) The system according to claim 13, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

15. (original, appealed) The system according to claim 13, wherein said artery is the brachial,

axillary, femoral or external iliac artery.

16. (original, appealed) The system according to claim 13, wherein said vein is the cephalic,

axillary, jugular, femoral or external iliac vein.

17. (amended, appealed) A method of performing hemodialysis on a patient comprising:

a. surgically inserting an arteriovenous shunt into a patient, wherein said arteriovenous

shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead

end being configured for subcutaneous connection to an artery by

anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and

depositing end, said depositing end being configured for insertion through a

vein into the right atrium of the heart, wherein said venous outflow catheter

has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft

to said venous outflow catheter, said cuff comprising an inlet in blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said arterial graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first

diameter and said venous outflow catheter second diameter;

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said arterial graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter

which is located in the right atrium and the blood is directly deposited into the right

atrium.

18. (previously presented, appealed) The method according to claim 16 wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

19. (original, appealed) The method according to claim 16, wherein said artery is the brachial, axillary, or femoral, external iliac artery.

20. (original, appealed) The method according to claim 16, wherein said the vein is the axillary, jugular, femoral or external iliac vein.

STATUS OF AMENDMENTS

Subsequent to the final rejection and prior to appeal brief, amendments to claims 2, 3, 7, 10, 18, 19 and 20 were made. These were made in compliance with the specifications so that the claims are in proper form.

SUMMARY OF CLAIMED SUBJECT MATTER

An apparatus for positioning a arteriovenous graft and catheter used for subcutaneous access to the vascular system of a patient. The hybrid

arteriovenous shunt is surgically created and comprises a flexible graft and a venous outflow catheter connected to the graft via surgical anastomosis over a cuff. As defined in independent claims 1, 13, 17, the present invention consists of three components: 1. an arterial graft connected to an artery by anastomosis 2. a single lumen venous outflow catheter which is inserted through the vein into the right atrium of the heart and 3. a cuff connecting the arterial graft to the venous outflow catheter. Claim 1 and 13 describe the components of the hemodialysis arteriovenous shunt and claim 17 describes the three components of the arteriovenous shunt and method of operation where the blood is taken from the arterial graft and purified through the machine and is then deposited directly into the right atrium. Refer to page 1 of the specification patent application publication dated September 29, 2005 [0008-0033] and refer to abstract on the cover page and diagrams fig. 1, fig. 2 and fig. 3 of the patent application.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Rejection under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1,13, and 17 must be shown or the feature(s) canceled from the claim. Applicant illustrates and argues that the venous outflow catheter ,12 , is 1mm smaller in diameter than the PTFE graft , 11. However, applicant has not specifically illustrated the graded inside diameter of the cuff to show that it accommodates the varying diameters of the tubes. A "graded" surface indicates a sloping surface, which applicant has not illustrated commensurate in scope with the claims.

2. Claims 1-5,7-10,12-14,17,and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

3. Claims 6,11,15,16,19, and 20 are rejected under 35 U. S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, in further view of US 5,591,226 to Trerotola et al.

4. Claim 10 is rejected under 35 USC 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.

ARGUMENTS

BACKGROUND

A conventional arteriovenous shunt is a subcutaneous conduit connecting an artery to the vein so that the blood flows continuously through the shunt at arterial pressure into the thin walled veins which are used to a low pressure flow. The graft is used for hemodialysis purpose in end stage renal failure patients. The blood is taken from the conduit dialyzed and injected back into the venous system. Arteriovenous graft patency rate decreases to 60% in the first year to 20

% in three years. The conduit is made of PTFE graft and 80 % of the failure rate is caused by stenos is at the venous end of the graft. (Morbidity and mortality of dialysis. NIH consensus Statement 1993; 11:1-33) The high flow rate from the shunt into the vein at the point of anastomosis to the vein results in vein wall vibration and injury to the vein wall resulting in neo-intimal hyperplasia which causes narrowing of the vein, thrombus formation and graft malfunction. In 1976, LD Baker Jr. teal were the first to use an expanded polytetrafluoroethylene graft in arteriovenous shunt on 72 patients and it is still in use today (see fig 4).

High failure rate prompted inventors to design arteriovenous access to avoid neo intimal hyperplasia. Squitieri believed neo-intimal hyperplasia is caused at the venous anastomosis and patented a device in 2003 where he positioned the venous outflow catheter within the vein to avoid anastomosis. Trerotola in 1977 invented a stunted graft and positioned the venous end of the graft within the lumen of the vein so as to avoid the anastomosis. The fact remains that anastomosis is not the main factor for neo-intimal hyperplasia. It is the vein wall injury from high flow at arterial pressure, which causes vein wall injury and neo-intimal hyperplasia, thrombosis and graft failure. The applicants of the present art positioned the venous outflow catheter in the right atrium to avoid anastomosis and vein wall injury from the high volume blood flow at arterial pressure and dialyzed blood at high pressure.

Rejection of drawing

1.Rejection under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1,13, and 17 must be shown or the feature(s) canceled from the claim. Applicant illustrates and argues that the venous outflow catheter ,12 , is 1mm smaller in diameter than the PTFE graft , 11. However, applicant has not specifically illustrated the graded inside diameter of the cuff to show that it accommodates the varying diameters of the tubes. A "graded" surface indicates a sloping surface, which applicant has not illustrated commensurate in scope with the claim

Response to Rejection of drawing

In regards to this rejection to the drawings under 37 CFR 1.83(a). The cuff of claim 1, 13 and 17 has a flat surface, which is 1 mm in thickness, wraps around the venous outflow catheter at the inlet end and is surgically anastomosed in an end to end

fashion to the arterial graft. Since the cuff does not cover the arterial graft, it does not have a sloped surface.

1) In figure 1, the venous outflow catheter is number 11 and the arterial graft is number 12. However the examiner has reversed these in the rejection, mislabeling the arterial graft as number 11 and venous outflow catheter as number 12. The examiner has misunderstood that the cuff defines a graded inside diameter. It means that the cuff brings together the arterial graft and venous outflow catheter conduits which are varying diameters. The diameter of arterial graft in the present invention is 1mm more in diameter than the venous outflow catheter and the two are brought together by surgical anastomosis of the venous outflow catheter, cuff, and the arterial graft. This is very clear in the specifications. As the cuff has no graded surface it is submitted that this rejection of claim 1,13 and 17 be withdrawn.

Rejection

Rejection Of claims 1-5, 7-10, 12-14, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

Response to Rejection

The examiner states that Squitieri's device is substantially similar to the claimed invention of the applicant. In claim 1, Squiteiri discloses an arteriovenous shunt system comprising an arterial graft (53) with a lead end (62) anastomosed to an artery and terminal end connected to needle access site (80), which acts as a connecter that corresponds to applicant's cuff. The system further comprises a venous outflow catheter (65) with an outflow end that is capable of being inserted through a vein (40) into the right atrium of the heart (see figs 6-9) and an inflow end that is connected to connector (80) (see column 4). The access site 80, corresponding to applicant's cuff, directs passage of blood from the arterial catheter to the venous catheter, and is in communication with

the terminal end of the arterial graft and the inlet end of the venous catheter (see figs 6-9,colum 5,lines 19-60).

The claimed invention is different from Squiteiri in the following ways:

1. Squiteiri recognized that the neo-intimal hyperplasia at the anastomotic site accounts for 60 – 80 % shunt failure - see column 6, line 80. He positioned the venous outflow catheter into a large vein to avoid anastomosis of the graft with the vein (Column 6, line 65, Column 3, fig 7 and 8) Claim 16, 8 and 1 – The venous outflow catheter of Squiteiri (65) remains in the **unnamed vein** whereas in our claimed invention, (claim 1,13,17) the venous outflow catheter remains within the right side of the heart, called right atrium. Squitieri's invention was patented because of the position of the venous outflow catheter within the unnamed vein and therefore the length of the catheter in Squitieri's invention is shorter than the claimed invention. Claims 16,8 and 1 in Squitieri's patent puts a limitation on Squitieri's invention with regard to the length of the catheter and his claims make the length of the catheter in Squitieri's invention shorter than our invention because our catheter has to go to the heart. Because of the claim limitation length of the venous outflow catheter in Squitieri's invention, his catheter cannot be advanced beyond the **unnamed vein** to any other position. Therefore any change in the position of Squitieri's venous outflow catheter suggested by the Examiner is incorrect, irrelevant, and will invalidate Squitieri's patent. The examiner cannot suggest a change in the position of the venous outflow catheter that even in the inventor, Squitieri, has never described in his own patent.

   The examiner has to shown any evidence that there is teaching in Squitieri's art for modification. The law requires that there must be some teaching in the prior art for modification. (MPEP 2143.01 in re Kahn, 441 F.3d,977,986,78 USPQ2d 1329,1335 (Fed Cir.2006). The examiner has not given any reason for expected beneficiary results, or some advantage that would come from the modification of Squitieri's art versus claimed invention. The law requires there should be some advantage or expected beneficial results from modification of the prior art. Sernacker, 702 F.2d 989, 994-95,217 USPQ 1,5-6 (Fed Cir 1983). In the absence of teaching or evidence of some advantage or expected beneficial results, one skilled in the art would not be motivated to modify Squitieri's art.

   The connector (80) in Squitieri's invention (see fig 9) also has 2 metallic chambers with a silicone membrane that connects the two conduits. In the applicants claimed invention, the cuff is structurally different because it will be made of biocompatible material and will cover the venous outflow catheter

only. The cuff connects the venous outflow catheter to the arterial graft by surgical anastomosis.

The examiner stated that Squiteiri discloses that the arterial and venous catheters may be

connected in various manners by cuffs that may comprise a cylindrical shape (see figs 2, 4, 6, 9,

11, 12, 14 (Squitieri et al) US .

In response to this, Fig 2 in Squitieri's patent, represents a reservoir mounted within a plastic or metal frame (see column 4, line 55) . Fig 4, columns 5, line 15 describes a glued connection between PTFE graft and silicone tubing that is a venous outflow catheter, wherein the PTFE tubing is inserted into the enlarged portion of venous outflow catheter. In our claimed invention, the venous outflow catheter is 1 mm smaller in diameter than the arterial graft and is not inserted into the arterial graft (see fig 1 of the claimed invention). Fig 6. in Squitieri's patent describes an arterial port with needle accessible portions made of silicone. In the claimed invention there is no reservoir and no needle puncture sites in the cuff. In fig 9 (Squiteiri) (see column 6, line 5) there is a dual needle access site (80), two reservoirs which are used for dialysis purpose using two needles. In the claimed invention there are no dual access needles sites on two reservoirs. Fig 11, column 6, page 20 (Squitieri) describes a quick coupler joining the PTFE graft to the port. the needle access site (20) Squitieri is not present in our claimed invention. In the claimed invention there is no needle port and there is no needle access site. Fig 12, line 30 (Squitieri) describes a port with needle access site which is different from the claimed invention. Fig 14 (Squitieri) (column 6, page 55) describes a cuff PTFE graft which is sewn to a vein. In Squitieri's invention, the venous outflow catheter enters through the PTFE graft into the vein and this is different from the claimed invention; our venous outflow catheter does not go through the PTFE. Various types of cuffs described by Squiteiri are structurally different than that of claimed invention.

Rejection by examiner relating to diameter of arterial and venous catheters:

With regard to claims 1, 4 ,5,8,9,12,14 and 18 with respect to diameters of the arterial and venous catheters, Squiteiri discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see column 3,line 60 to column 4,line 15). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform

differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). It appears that the device and method disclosed by Squiteiri would perform in the same manner as claimed by the applicant.

Response to rejection by examiner relating to diameter of arterial and venous catheters

Squitieri's invention (column 4, line 10,15), the arterial graft has a length of several centimeters and is 4-7 millimeters in diameter. The arterial end connecting to the artery is 4 millimeters. The venous outflow catheter length and diameter are not mentioned, but as in claim 1(column 8,line 30) the catheter end is positioned within the vein and the diameter is less than the inner diameter of the vein so that the blood flows into the vein and through the vein, around an outer surface of the catheter. In our claimed invention (claim 1) the arterial graft has a specific diameter and the venous outflow catheter has a second specific diameter. The venous outflow catheter is inserted through the vein into the right atrium of the heart. With regard to our invention, Claim 4 speaks of the arterial graft diameter from 2 millimeter to about 8 millimeter and the length is 20-60 cm. Claim 5 also gives the diameter specifications (6-8mm) and the length specifications (40cm). Claim 8 describes the diameter of venous outflow catheter (1-7 mm), and length specifications (20 cm to about 80 cm). Claim 9 describes the diameter of venous outflow catheter (5 mm to about 7 mm), and length specifications (40 – 60 cm). Claim 12 describes that the venous outflow catheters diameter is 1 mm smaller than the arterial graft. Claim 14 also shows that venous outflow catheter has a diameter of about 1 mm smaller than the arterial graft. Claim 18 also states that the venous outflow catheter has a diameter of about 1 mm smaller than the arterial graft.

The difference between claimed invention and Squitieri's invention is that Squitieri only gives the diameter of the arterial graft (4-7mm) (see column 4 line 20) and the applicant's invention provides specific diameters of the arterial graft and venous outflow catheter. The length of the venous outflow catheter in Squitieri's invention is limited and remains shorter than that of the claimed invention, because, in the claimed invention the venous outflow catheter is placed in the right side of the heart (see claim 1,13 and 17 of the claimed invention) so the length is longer than that of Squitieri's invention. The principles of operations are also different. In Squitieri's art the blood flows into the vein (see column 8, claim 1, line 35) whereas in the claimed invention the blood flows into the right atrium of the heart and thus the mode of operation is different than that of the applicant's invention (see also claim 17 of applicants invention, abstract patent application, and Specification page 2, line 0025,line 0033, and page 3, 0056,0058, page 4 claim 1). The mode of operation is quite evident and different from

Squitieri's. It would be obvious to someone having ordinary skill in the art that Squitieri's invention can only deposit blood into the vein.

See MPEP 2144.04(IV)A and Gardener Vs. TEC Systems, INC., 725 F.2d 1338,220 USPQ 777 (fed. Cir. 1984), cert denied, 469 U.S. 830,225 USPQ 232(1984). In this reference the circuit court has clearly stated that when two arts perform differently the claimed invention is patentably distinct from the prior art device. In Squitieri's invention the vein is subject to continuous high blood pressure flow and the high pressure of dialyzed blood hitting the vein wall. Vein wall injury leading to neo intimal hyperplasia and stricture of the vein is bound to occur. As reported in the literature neo intimal hyperplasia is responsible for 80% of graft failure. Therefore the expected success rate will be lower in Squitieri's art than in the claimed invention. In the claimed invention, the shunt will not be clotted or obstructed from neointimal hyperplasia. The life of our shunt will be much longer rate of graft failure will be lower. There are no substantive reasons to reject claims 1,4,5,8,9,12,14, and 18 therefore these rejections should be withdrawn.

Rejection by examiner with regards to Parks et al.

Parks discloses a medical fluid handling apparatus with a ferrule or connector 70 that receives and joins different sized conduits with graded interior wall regions 82, 84, 86 (see fig 7, column 4, lines 55-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a graded interior surface as disclosed by Parks to the connector between the arterial and venous catheters in the vascular access system disclosed by Squitieri in order to accommodate inserts of various diameters, as taught by Parks.

Response to rejection by examiner with regards to Parks et al.

Parks' invention is a non-analogous art. It belongs to the gastrointestinal system, whereas the claimed invention pertains to the arteriovenous system. Parks ferrule is disposed within the conduit (column 3, line 10, fig 12) Parks ferrule has a graded surface because it joins various conduits. In the claimed invention our cuff has a flat surface. It covers only one conduit namely the venous outflow catheter and is surgically sutured to the arterial graft. Parks invention is used for the creation of a gastrostomy tube, whereas the claimed invention creates an arteriovenous shunt for hemodialysis purposes. Parks' ferrule (cuff) is made from hard non-deformidable material such as plastic, metal, or glass. See page 4, line 25. **If Parks' cuff is used in claimed invention, it has to go within the lumen of the arterial graft and the venous outflow catheter. Park's**

cuff has a ridged inner surface and will act as a foreign body within the lumen of the arterial graft and venous outflow catheter leading to obstruction of the flow of blood, thrombosis and destruction of the function of the claimed invention. Blood will not flow through it in with smooth laminar flow as it would through our cuff. It is this turbulent flow and obstruction to the flow of blood that would cause thrombosis (clotting) and destruction of function of the claimed invention. It would cause the same destructive result to the flow of blood in Squitieri's invention. Combining Squitieri's and Park's references would lead to destruction of the function of such a device , because Park's cuff has to go within the two conduits of Squitieri's art leading to obstruction of the blood flow, clotting of the shunt, and destruction of the function of the shunt and our claimed invention. It would not be obvious to the applicants or someone with ordinary skill in the art to consider Parks' art at the time the claimed invention was made (refer KSR International Co. Vs Teleflex INC., 550 U.S., 82 USPQ2d 1385, 1397 (2007). This reference is irrelevant and the examiner has made a substantial error in citing this reference. One in the ordinary skill in the art will not be motivated and it is not obvious to someone of ordinary skill to combine two references which would lead to the destruction of the function of the claimed invention.

Rejection by examiner with regards to the materials in claims 2, 3, and 7

The examiner states that Squitieri discloses an embodiment, tubing or cuff (69) which is made of PTFE (polytetrafluoroethylene), a biocompatible , flexible material.

Response to rejection by examiner with regards to the materials in claims 2, 3, and 7

In the claimed invention, the arterial graft (claim 2) can be made of a biocompatible material and the word flexible has been removed. Claim 3 is amended. The words polytetrafluoroethylene (PTFE) and 'other' has been removed and replaced with biocompatible material. The AV shunt of claim 2 is made of biocompatible material. Amended claim 7 , states the cuff, is made of polyethylene terephthate or other biocompatible materials (claim 7). These are now amended claims, therefore any rejections with regard to the unamended claims 2, 3 and 7 should be withdrawn.

Rejection by examiner with regard to claim 13

The examiner states that Squitieri also discloses that the arteriovenous graft system which may be connected to a hemodialysis machine (not shown), meeting the limitations of the claim (see column 4 , lines 60-64)

Response to rejection by examiner with regard to claim 13

The goal of both inventions is to perform hemodialysis. Squitieri does not retain the authority over all hemodialysis devices utilizing an arteriovenous graft because his device does that. This does not limit claim 13. The examiner cannot limit claim 13 of the claimed invention, because it performs dialysis which is the goal of Squitieri's art as well. The basis for the rejection is irrational and the rejection should be withdrawn.

With regard to claim 13 of the claimed invention it describes the arteriovenous shunt for performing hemodialysis on patients comprising of arterial graft connected to the artery, single lumen venous outflow catheter deposited into the right atrium and a connecting cuff.

The differences between claimed invention and Squitieri's art have already been described, being both structural and operational. The arteriovenous shunts of Squitieri's and claimed invention are used for hemodialysis purpose and in both of the inventions the dialysis machine is used for dialysis. The goal of the two inventions is to perform dialysis. There is no reason to reject claim 13, because of the operational and structural differences of the two inventions already presented, therefore the rejection of claim 13 should be withdrawn.

The combined reference of Squitieri and Parks do not match the claimed invention. Squitieri taught and suggested that the venous outflow catheter remain within the vein. Parks' art is irrelevant and would lead to the destruction of the operational function of the claimed invention. The combined references do not teach or suggest any modification of the prior art. Therefore it would not be obvious to one with ordinary skill in the art to use the combined references which would lead to the destruction of the functioning of the claimed invention. The applicant's disagree with the examiner's

remarks (see page 2) that claimed invention is unpatentable over Squitieri's and Parks arts.

Rejection to claim 6,11,15,19,20

Claims 6, 11, 15, 16, 19 and 20 are rejected under 35 U.S.C 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399, 173 to Parks et al, further in view of US 5, 591,226 to Trerotola et al. In the specification and figures, Squitieri and Parks' disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of the particular arteries and veins that are used to connect to the arteriovenous system. Squitieri is silent as to the particular vessels used, but it is well known in the art of arteriovenous grafts that one may select any given vessel based on the suitability for its purpose. Trerotola discloses a stent-graft that may be deployed between many vessels within a patient, and discloses a graft between a brachial artery and an axillary vein (see fig 9A and accompanying text). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect the arteriovenous graft system disclosed by Squitieri to the brachial artery and axillary vein as disclosed by Trerotola in order to create blood flow between the selected vessels, as demonstrated by Trerotola.

Response to Rejection to claim 6,11,15,19,20

The Examiner agreed that Squitieri does not mention the name of the arteries and the veins in the construction of his arteriovenous shunt. The examiner refers to Trerotola who makes a brachioaxillary shunt with stunted graft as shown in fig 9A. The graft is inserted within the lumen of the axillary vein to avoid anastomosis. Trerotola's art is different from the claimed invention because the claimed invention does not use the graft within the vein but places the venous outflow catheter through the vein into the right atrium. The veins that are used for routing the catheter into the right atrium of the heart are found in claim 11, 16 and 20 and the arteries used in the construction of the hemodialysis apparatus are found in claim 6, 15, 19. In Trerotola's art the arterial blood from the shunt goes into the axillary vein and if this shunt is used for dialysis purposes, the ejected blood at high pressure will go into the axillary vein leading to vein injury, neo intimal hyperplasia and graft failure. There is no reason to reject claim 6, 11, 15, 16, 19, and 20. The names of the particular arteries and the veins, have to be mentioned to construct the arteriovenous shunt. It is obvious to ones with ordinary skill in the art as the applicants are, that the particular vessels have to be named to construct an arteriovenous shunt. In the claimed invention the arteries that are used are mentioned

in claim 11, 15 and 19, and the veins are mentioned in claim 6, 16 and 20. The combined references of Squitieri, Parks and Trerotola would not construct an invention as of our claimed invention and lead to the destruction of the function of Squitieri's and our claimed invention. One skilled in the art would not find obvious or be motivated to combine the three references. There the rejections of claim 6,11,15,19, and 20 should be withdrawn should be withdrawn.

Rejection to claim 10

Rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over US 6, 102,884 Squitieri in view of US 5,591, 226 to Trerotola et al.

Response to rejection of claim 10

Claim 10 is amended wherein the venous outflow catheter is made of biocompatible material. Therefore the rejection based on the use of polyurethane in the Trerotola stent graft should be withdrawn and rejection 10 should be withdrawn.

Rejection to claim 17

Rejection of claim 17 under 35 U.S.C. 103(a) as being unpatentable over US 6, 102, 884 to Squitieri in view of US 5, 399, 173 to Parks et al, further in view of US 5, 509,897, Twardowski at al.

With regard to claim 17, the cited prior art discloses the method substantially similar as claimed by applicant (see rejection above). In particular, Squitieri discloses that the graft may be surgically inserted (see column 7,lines 24-45), connected to a hemodialysis machine (which, by definition, purifies blood)

collect blood through the arterial catheter, send the blood through a dialysis machine, and collect blood from the dialysis machine and return it to the patient via the venous catheter (see column 4,lines 50-64). Squitieri fails to disclose that the treated blood is deposited directly into the right atrium, but suggests such an arrangement in the illustrations of figs 7 and 9 which shows venous catheter 65 extending towards the heart via vena cava 40. Blood flows from the vena cava into the right atrium. Nonetheless Twardowski discloses an apparatus and method for hemodialysis which a venous catheter comprises a distal end(138a) disposed within the right atrium delivering treated blood to the right atrium in order to provide a long term indwelling catheter. Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to advance the catheter disclosed by the cited prior art deeper into the patient's vasculature to the right atrium, as disclosed by Twardowski in order to provide a long term indwelling catheter without major drawbacks as taught by Twardowski et al.

Response to rejection of claim 17:

Twardowski's invention is a hemodialysis catheter where the blood remains stagnant within the catheter when not in use for dialysis. The catheter has two lumens (see page 7 of description of the invention and fig 3). The catheter has three parts (See fig 11,) ;part 1 goes through the vein into the right atrium. The second part is tunneled under the skin (140 fig 11) and has two cuffs (154, 156) and the third part exits the skin and remains with two ports outside the skin on the chest wall (See fig 5) . Through port 2, the blood is taken out and passed to the hemodialysis machine and is connected to the first port which returns the blood to the venous side. The catheter tip (138) remains in the right atrium as shown in fig 9. Therefore the multilumen hemodialysis catheter of Twardoski is also called a cuffed tunneled dialysis catheter.

The applicant's art is different from Twardowski art in the following ways:

1.The claimed invention is a sub-cutaneous arteriovenous shunt, where the blood is continuously

flowing through the shunt, at arterial pressures, into the right atrium. In Twardowski's catheter

the blood flows at high pressure

through the catheter at the time of dialysis only therefore it's not a sub-cutaneous arteriovenous shunt.

2. Twardowski's catheter is a double lumen catheter where as claimed inventions venous outflow catheter is a single lumen catheter (See claim 1, 13 and 17).

3. Squitieri's venous outflow catheter is also a single lumen catheter which goes within the lumen of the vein whereas in claimed invention the catheter goes into the right atrium.

4. Combining Squitieri's and Twardowski's devices is physically impossible because Twardowski's catheter is a double lumen catheter and part of the catheter exits outside the skin as two ports. Squitieri's is a single lumen catheter. The combination is physically impossible because a single lumen catheter of Squitieri and double lumen catheter of Twardowski cannot fit together. The sub-cutaneous shunt of Squitieri cannot be constructed because the two ports of Twardowski's hemodialysis catheter are outside the skin on chest wall. Those with ordinary skill in the art would find it impossible to combine Twardowski 's and Squitieri's references.

As described before Parks' reference is non-analogous and has a graded cuff which if used in applicant's art it has to be placed within the lumen of the conduits which will lead to obstruction of blood flow, clotting of the invention and malfunction; thereby destroying the function of the claimed invention. If Parks cuff is used in Squitieri's art it will lead to destruction of his art.

Squitieri taught that the catheter remained within the vein. Therefore these three references are improper and cannot match the claimed invention. Claim 17 of the claimed invention describes the hemodialysis apparatus where the blood is taken from the arterial graft to the dialysis machine and from the machine to the venous outflow catheter which deposits the dialyzed blood into the right atrium. The claimed device is structurally different from Squitieri as described before and the method of operation is different from Squitieri where the blood is deposited into the vein after hemodialysis. Claim 17 is a novel one, because of the positioning of the catheter in the right atrium. It is not possible to make the claimed invention by combining the above three references because that will cause destruction of function of the claimed invention and Squitieri's art, therefore rejection 17 should be withdrawn.

Combining the four references of Squitieri, Parks, Twardowski and Trerotola does not make the claimed invention. The examiner has not shown any evidence of some reason to combine the four references. The test of teaching suggestion and motivation does not exist in the prior four arts. A person of ordinary skill in the art would not combine the four references, as the reference of Park's and Squitieri's will lead to the malfunction and destruction of Squitieri's art and claimed invention and also combining

Twardowski's with Squitieri's art is physically impossible. Furthermore one with ordinary skill in the art will not combine Squitieri's and Twardowski's art because that will not create a subcutaneous arteriovenous shunt as the catheters have different numbers of lumen; Squitieri's art has a single lumen and Twardowski's art has a double lumen and the catheter hangs out of the skin on the chest wall as two ports. Therefore it will be impossible physically to combine Squitieri's art and Twardowski's art. Thus combining the four arts does not make an invention as that of the applicants'.

SECONDARY CONSIDERATIONS

The HeRO ™ Vascular Access Device is used for hemodialysis is structurally and functionally identical to claimed invention. It performs the function in the same way as that of our claimed invention (Doctrine of Equivalent). An FDA approved clinical trial was conducted by Dr. Katzman, H. and Dr. Chris Stout et Al. Dr. Katzman presented the data before the society of cardiovascular surgery in March 2008. The manufacturer of the device is Hemisphere Inc. The clinical trial was conducted to evaluate the HeRO device with respect to bacteremic rate, adequacy of dialysis and patency. The data obtained is applicable to our claimed invention.

When comparing bacteremic (infection) rates, the graft arm HeRO (the HeRO device combined with the arterial graft) had a bacteremic rate of 0.6 at 1000 days. Standard arteriovenous graft infection rates are 0.11 at 1000days. Standard tunneled cuffed dialysis catheters have a bacteremic rate of 2.3 at 1000 days. The infection rate in the HeRO device is lower than in the AV graft and cuffed tunneled dialysis catheter (Table 3, page 5 "HeRO ™ Vascular Access Device: A Long Term Solution for Access-Challenged Patients." Katzman et al Presented at Society for Cardiovascular Surgery March 2008, See Abstract Exhibit 1 of Declaration of Oath).

The overall patency rate, which is the rate functioning of the arteriovenous shunt of the HeRO device, is also higher than cuffed tunneled dialysis catheter (Refer to table 4 of Katzman et al).

The adequacy of the dialysis as measured by (Kt/V), which is an index of clearing of the impurities of the blood, demonstrates that the HeRO device is superior and had a (Kt/V) of 1.7 versus a cuffed tunneled dialysis catheter (1.29-1.46) and the AV graft which is (1.37-1.62). The National Kidney Foundation Dialysis Outcome Quality Initiative-K/D OQI provides a target value for adequacy of dialysis which is 1.4 (higher score correlates to higher clearance of the impurities from the blood). Thus the functioning of the HeRO device is better than the cuffed tunneled dialysis catheter. The study further revealed that the KT/V had an impact on the mortality. A decrease of 0.1 Kt/V is associated with a 7% increase in mortality (more deaths) Refer to table 6, Katzman et al.

It is very clear that the claimed invention will have a better patency rate, reduced infection rate and a reduced mortality as compared to Twardowski's cuffed tunneled dialysis catheter. The decreased mortality is a new and unexpected finding.

Chris Stout presented the clinical study of HeRO device before the Society for Clinical Vascular Surgery in March 2009 with patients of central vein occlusion. The 52 patients underwent the procedure and the HeRO device was successfully placed in 50 patients who had successful dialysis; this is an unexpected finding that the HeRO dialysis catheter can be effective in central venous occlusion in patients with chronic renal failure.

The results of the study show new and unexpected findings that claimed invention will better dialysis and long patency as compared to cuffed tunneled catheter of Twardowski's art. To applicant's knowledge Squitieri's art has not gone into clinical trials and Trerotola invention is an experimental one.

This long felt and unsolved need for avoiding 80% graft failure from neo-intimal hyperplasia can only be solved if the venous outflow catheter is positioned in the right atrium. The vein wall damage will not occur because blood goes directly into the heart and not into the vein.

The study demonstrated superior results of claimed invention, unexpected and new results, and the claimed invention met all four Graham's in (Graham v. John Deere Co.) respect to the scope and content of the prior art, the difference between claimed invention and the prior art and the level of ordinary skill is the pertinent art, secondary considerations, long felt unsolved need and failure of others. The problem of the neo-intimal hyperplasia can be eliminated only with the claimed invention and therefore the long felt unsolved need can be resolved.

Commercial Success

Dr. Katzman is going to present the early commercialization of the HeRO vascular device at the annual convention of the Society of Vascular Surgery in June 2009 in Denver, Colorado.

The claimed invention satisfied four of Graham's factors (35 U.S.C. 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

First the scope and content of prior art is outlined in the background section of the appeal brief. Second, the difference between the prior art and claimed invention is outlined in various sections of the appeal brief. Third, the level of ordinary skill in the art is outlined in multiple sections in the Arguments section of the Appeal Brief. Fourth, secondary considerations have been outlined. In addition, the long felt and unsolved needs in the art have been discussed.

CONCLUSION

In view of the secondary consideration, new and unexpected results, and superior performance of the claimed invention as demonstrated through Dr. Katzman 's and Dr. Stout's studies. Satisfying all four factors of Graham's unobviousness, the primafacie case of obviousness is rebutted . On the basis of the novelty and unobvious features of the claimed inventions, all the rejections 1-20 should be withdrawn and the patentability should be granted.

An appeal brief is submitted in a proper form for the consideration of patentability by the appeals board. If you have any questions please call Nazir Khan at 312-590-0589 or 312-329-1100 or Iftikhar Khan at 312-730-8796.

Thank you.

Iftikhar Khan MD

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Iftikhar Khan
5/23/05

Nazir Khan MD

150- Glenmora

Burr Ridge, IL

Nazir Ahmad Khan
5/23/05

VIII) Claims Appendix. Copies Of The Claims involved in the appeal are attached.

1. (amended, appealed) An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

c. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood communication with an outlet:

i. said inlet being disposed about and connected to said terminal end of said

arterial graft; and

ii. said outlet being disposed about and connected to said intake end of said

venous outflow catheter; wherein said cuff provides a secure fit for

said arterial graft first diameter and said venous outflow catheter second diameter.

2. (previously presented, appealed) The arteriovenous shunt of claim 1 wherein said arterial graft

is made of a biocompatible flexible material.

3. (amended, appealed) The arteriovenous shunt of claim 2, wherein said biocompatible

flexible material is polytetrafluoroethylene(PTFE) or other biocompatible material

4. (appealed) The arteriovenous shunt of claim 1, wherein said arterial graft has a

diameter from about 2 mm to about 8 mm and a length from about 20 cm to about 60 cm.

5. (appealed) The arteriovenous shunt of claim 4, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length of about 40 cm.

6. (appealed) The arteriovenous shunt of claim 1, wherein said artery is the brachial,

axillary, femoral or external iliac artery.

7. (Appealed) The arteriovenous shunt of claim 1, wherein said cuff is

polytetrafluoroethylene or polyethylene terephthalate.

8. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter

has a diameter from about 1 mm to about 7 mm and a length of from about 20 cm to

about 80 cm.

9. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter

has a diameter from about 5 mm to about 7 mm and a length of from about 40 cm to

about 60 cm.

10. (amended, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of other biocompatible materials.

11. (appealed) The arteriovenous shunt of claim 1, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

12. (previously presented, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

13. (amended, appealed) A system for performing hemodialysis on a patient comprising: a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and

depositing end, said depositing end being configured for insertion through a

vein into the right atrium of the heart, wherein said venous outflow catheter

has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft

to said venous outflow catheter, said cuff comprising an inlet with blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said subcutaneous graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter;

14. (previously presented, appealed) The system according to claim 13, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

15. (original, appealed) The system according to claim 13, wherein said artery is the brachial,

axillary, femoral or external iliac artery.

16. (original, appealed) The system according to claim 13, wherein said vein is the cephalic,

axillary, jugular, femoral or external iliac vein.

17. (amended, appealed) A method of performing hemodialysis on a patient comprising:

a. surgically inserting an arteriovenous shunt into a patient, wherein said arteriovenous

shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead

end being configured for subcutaneous connection to an artery by

anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and

depositing end, said depositing end being configured for insertion through a

vein into the right atrium of the heart, wherein said venous outflow catheter

has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft

to said venous outflow catheter, said cuff comprising an inlet in blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said arterial graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first

diameter and said venous outflow catheter second diameter;

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said arterial graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter which is located in the right atrium and the blood is directly deposited into the right atrium.

18. (previously presented, appealed) The method according to claim 16 wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

19. (original, appealed) The method according to claim 16, wherein said artery is the brachial,

axillary, or femoral, external iliac artery.

20. (original, appealed) The method according to claim 16, wherein said the vein is the axillary, jugular, femoral or external iliac vein.

IX) Evidence Appendix: Copy of the declaration of oath with exhibit 1 and 2 are attached.

Declaration in Support of Application

1. We are the applicants in the above identified patent application

2.We declare the HERO™ (Hemodialysis Reliable Outflow) vascular access device, manufactured by Hemisphere Inc. company is a hemodialysis arteriovenous shunt identical to the applicants claimed invention. Clinical studies revealed new and unexpected results.

These results are a marked decrease in bacteremia rate versus currently used cuffed tunneled dialysis catheters and current arteriovenous graft literature.

Improved adequacy of dialysis and patency versus currently used cuffed tunneled dialysis catheters.

Please see Exhibit 1 and Exhibit 2 as supporting documents for the HERO™ device.

In patients with central venous occlusion, the HERO™ device has achieved a success rate for allowing dialysis in patients with no other option, 96.2% of the time (50/52 patients).

3. I declare that all of the statements made herein of my knowledge are true and that all statements made upon information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment , or both, under Section 1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing therefrom.

IX) Evidence Appendix: Copy of the declaration of oath with exhibit 1 and 2 are attached.

X) Related Proceedings Appendix

The copies of the court decisions are attached

Katzman, H. HeRO Vascular Access Device: A New Long-Term Dialysis Access Option for Access-Challenged Patients SCVS March 2008	**Objective:** The purpose of the study was to assess HeRO bacteremia and patency rates, adequacy of dialysis, and adverse events in graft-eligible and in "access challenged" subjects i.e., catheter dependent /poor-venous outflow subjects. **Methods:** The HeRO device consists of a 6 mm inner diameter (ID) ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous 5 mm ID nitinol reinforced silicone outflow catheter designed to bypass peripheral stenosis and exit into the right atrium via the IJ vein. Ninety HeRO subjects were enrolled in two study arms – access challenged (catheter arm) and graft-eligible (graft arm) subjects. Study endpoints included bacteremia and patency rates, adequacy of dialysis and adverse events. All results were compared to literature. **Results:** The data shows a marked decrease in the HeRO-related bacteremia rate in both study arms. The catheter arm HeRO-related bacteremia rate was 0.12/1,000 days versus IJ tunneled dialysis catheter (TDC) literature rate of 2.3/1,000 days. The graft arm HeRO-related bacteremia rate was 0.06/1,000 days versus graft literature rate of 0.11/1,000 days. HeRO patency rates (primary, primary-assisted, secondary and functional) in both study arms were better than TDC literature and equivalent to graft literature. HeRO adequacy of dialysis data (Kt/V 1.6-1.7) surpasses TDC literature (Kt/V 1.29-1.46) and was comperable to graft literature (Kt/V 1.37-1.67). Serious device/procedure-related adverse events were comperable to both TDC and graft literature. **Conclusions:** The HeRO device may be the best long-term access alternative for access challenged patients including those that are catheter dependent, are failing fistulas and grafts due to venous obstructions, have poor anatomy for a fistula or graft, or are receiving inadequate dialysis via a TDC.
Work, J. New Vascular Access Device Option for Catheter Dependent Patients ASDIN February 2008	**Purpose:** The purpose of this study was to evaluate catheter-dependent patients dialyzing with a new long-term access option, the Hemodialysis Reliable Outflow (HeRO™) vascular access device for device/implant procedure-related bacteremias compared to chronic tunneled dialysis catheter literature rates. HeRO is entirely subcutaneous and consists of a 6 mm inner diameter ePTFE upper arm graft connected to a 5 mm inner diameter nitinol-reinforced silicone outflow catheter that empties into the central venous system eliminating the need for graft to vein anastomosis, thus bypassing peripheral venous stenosis. **Methods:** This was a multi-center FDA regulated study designed on the premise that subjects considered catheter-dependent or poor candidates for fistula or graft due to inadequate venous outflow would experience a significant reduction in bacteremia rates with the HeRO device compared to a tunneled dialysis catheter. **Results:** The 36 subjects enrolled had on average 4.2 previous TDCs (range 1-16) and 1.7 previous bacteremias (range 1-4). As of 10/25/07, 8,450 HeRO days have accumulated with an average of 7.3 months of HeRO follow-up. The overall HeRO device/procedure-related bacteremia rate was 0.83/1,000 days compared to the catheter literature

10:15 am - 11:00 am

SCIENTIFIC SESSION 4 – DIALYSIS

Moderated by: Joann M. Lohr, MD & Anil Hingorani, MD

Learning Objectives:
- Describe recent trends in outcomes for arterivenous access procedures
- Recognize evolving strategies to improve treatment planning for arteriovenous access procedures
- Identify novel strategies to enhance outcomes for arteriovenous access procedures in patients with challenging venous anatomy

MP14. Hemoaccess Placement in patients with Challenging Central Vein Occlusion
Chris Stout, MD, Jean Panneton, MD, Marc H. Glickman, MD. Eastern Virginia Medical, Norfolk, VA, USA.

December 12, 2008

Hemoaccess Placement in patients with Challenging Central Vein Occlusion

Back to Annual Meeting
Back to Program

Chris Stout, MD, *Marc H. Glickman, md, Jean Panneton, MD.*
Eastern Virginia Medical, Norfolk, VA, USA.

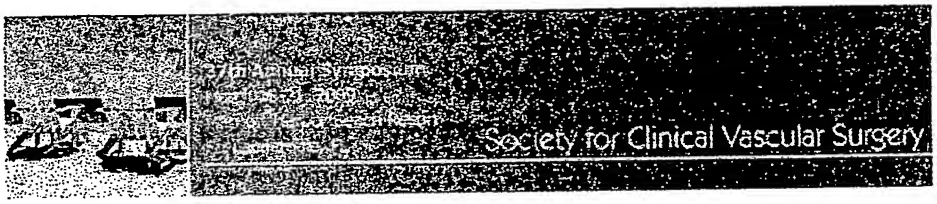
OBJECTIVES: The placement of hemoaccess devices in patients with central vein occlusion is becoming more challenging for surgeons. The incidence of catheter dependent patients on dialysis continues to rise. Catheter dependent dialysis is fraught with complications including higher morbidity and mortality when compared to conventional dialysis. The purpose of the abstract is to present experience with the HeRO access device, which returns the patient to a conventional graft like access.

METHODS: The HeRO device, a graft with a central outflow component designed to bypass central venous stenosis, consists of ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous nitinol silicone outflow component which exits into the central venous system. Prospective data included average number of prior access procedures, the degree and type of central vein occlusion, vessel anatomy and surgical implant location.

RESULTS: Fifty two patients have undergone attempted placement of the HeRO devic. Forty patients have had placement of the device after successful angioplasty of near central vein occlusion, four patients have had placement of the device within the subclavian veins with central vein angioplasty, one patient had placement of the device into the SVC through

a retroperitoneal approach for SVC and IVC occlusion, two patients had placement into large azygous veins, four patients had placement through recannalized central veins and internal jugular veins and two patients had unsuccessful placement attempts due to inability to recannalilze the central veins. Fifty patients have had successful placement of this device and of these forty-eight patients have had successful conversion from catheter dependent dialysis to conventional dialysis

CONCLUSIONS: HeRO is the first AV access device to offer significant alternative to patients who are catheter dependent for their dialysis due to central vein pathology. These are very complex and demanding patients. HeRo device offers a promising alternative for these patients allowing conventional dialysis to be achieved



X) Related Proceedings Appendix

The copies of the court decisions are attached

HeRO™ Vascular Access Device: A Long Term Solution for Access-Challenged Patients.

Howard Katzman MD

Notes

INTRODUCTION

Tunneled dialysis catheters (TDCs) are considered the last resort "long-term" vascular access option compared to arteriovenous fistulas (AVFs) and grafts (AVGs). TDCs cause a high incidence of catheter-related bacteremia because the TDC penetrates the skin barrier creating a route for contamination; TDC-related bacteremias increase patient morbidity and mortality and result in significantly increased hospital costs.[1] TDCs deliver less effective dialysis due to reduced blood flow rates and are plagued with frequent malfunctions. [2-4] Additionally, traditional TDCs may induce central venous stenosis, which can limit future AVF or AVG options.[5] Despite these disadvantages and the success of the Fistula First Initiative, the number of patients dialyzing on TDCs continues to increase. As outlined in the DOPPS studies, the number of prevalent patients dialyzing on catheters virtually doubled from 15.2% in 1996-97 to 28.2% in 2002-2003[6] and as recently as 2006-2007, the End Stage Renal Disease Clinical Performance Measure Project (ESRD CPM project) noted a 2% increase in TDC catheter prevalence. Furthermore, over 70% of ESRD patients initiate dialysis with a catheter.[7]

Tunneled catheter dependency as a result of central venous stenosis, which inhibits peripheral access placement, can be significantly decreased by implantation of the HeRO™ Vascular Access Device. The FDA has cleared the HeRO™ device for maintaining vascular access in those patients who have exhausted all other peripheral access options. This device combines the functional status of an ePTFE graft and tunneled catheter into a permanently implanted subcutaneous access. The HeRO™ device consists of a 6 mm inner diameter (ID) ePTFE graft component fitted with a titanium connector that is surgically coupled at the time of implant to a subcutaneous 5 mm ID braided nitinol reinforced silicone outflow component designed to bypass peripheral stenosis and exit into the superior vena cava/right atrial junction via the internal jugular (IJ) vein, see **Figure 1** and **Figure 2**. The outflow component is introduced into the IJ vein using standard Seldinger technique and tunneled subcutaneously to the delta/pectoral groove in the shoulder area. The HeRO™ ePTFE graft is then tunneled from the shoulder area to the lower portion of the upper arm just above the elbow. The outflow component is then connected to the graft via the silicone encapsulated titanium connector and lastly, a graft to brachial artery anastomosis is created in the same manner as a conventional upper arm ePTFE graft. The HeRO™ device requires a heal-in period to allow the ePTFE to incorporate into the surrounding tissue before it can be accessed. During this time, a patient may require a bridging TDC for dialysis. Once the HeRO™ device is ready for cannulation (per K/DOQI graft cannulation guidelines), it is accessed in the same manner as a conventional graft eliminating the need for special training at dialysis centers.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

KSR INTERNATIONAL CO. *v.* TELEFLEX INC. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 04–1350. Argued November 28, 2006—Decided April 30, 2007

To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be taken off the shelf and attached to any

702 F2d 989 In Re Howard Sernaker

702 F.2d 989

217 U.S.P.Q. 1

In re Howard SERNAKER.

Appeal No. 82-579.
Serial No. 916,018.

United States Court of Appeals,
Federal Circuit.

Feb. 28, 1983.

Michael F. Petock, Philadelphia, Pa., argued and filed briefs for appellant.

Associate Sol. Fred W. Sherling, Washington, D.C., argued for Patent and Trademark Office. With him on th Sol., Joseph F. Nakamura, Washington, D.C.

Before DAVIS, Circuit Judge, COWEN, Senior Circuit Judge, and NICHOLS, Circuit Judge.

NICHOLS, Circuit Judge.

1

This case is before us on appeal from the decision of the Patent and Trademark Office Board of Appeals (bo decision, the board affirmed the examiner's rejection, under 35 U.S.C. Sec. 103, of claims 1-6 and 8-11 in a application serial No. 916,018, filed June 15, 1978, entitled "Embroidered Transfer and Method of Making." comprise all the claims in the case. We reverse.

2

* Background

A. The Invention

3

Appellant has invented a type of embroidered emblem and a method of making the same. Claims 1 and 10, independent claims in appellant's application, are representative of the method and of the emblem, respecti

4

1. A method of making an embroidered transfer or emblem comprising the steps of:

5

(a) embroidering a pattern on a portion of a substrate while using thread free from oil and with said thread single color and in an amount so that a portion of the pattern is sculptured by having a greater thickness th portion of the pattern,

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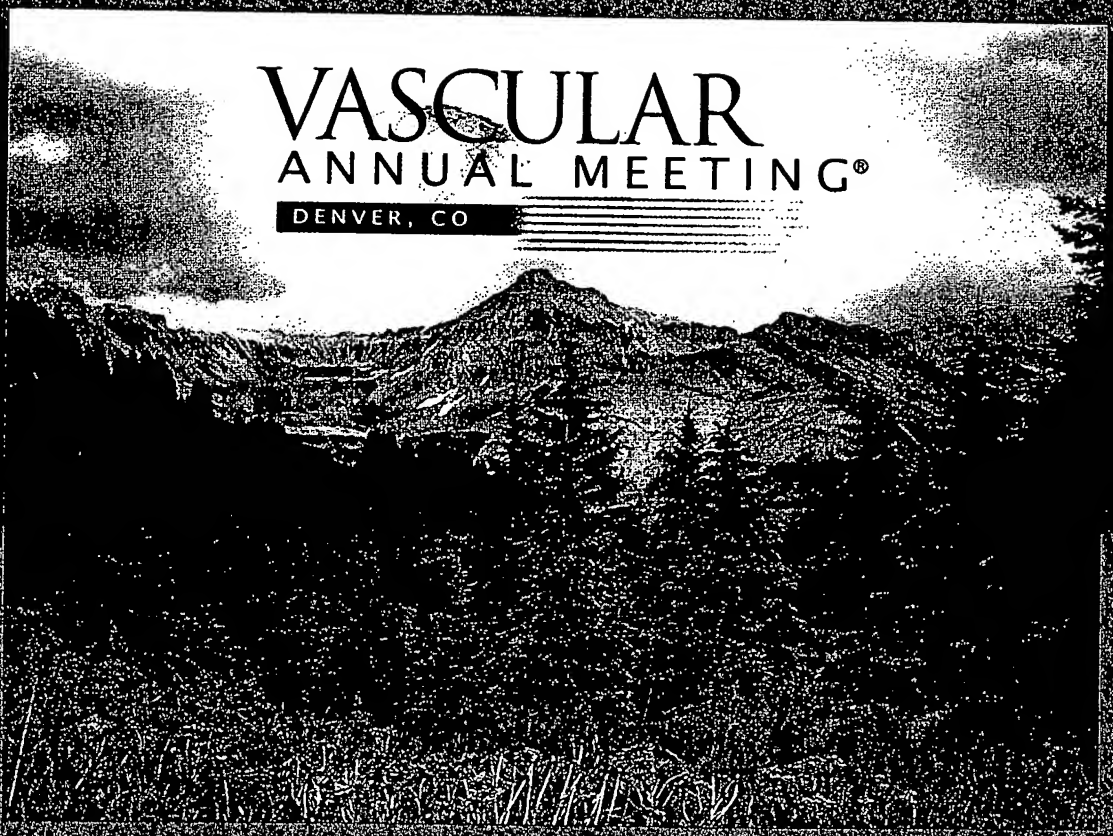

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Author Disclosures: J. Vos, None; G.J. De Borst, None; T.T.C. Overtoom, None; J.P.M. de Vries, None; E.D.W. van de Pavoordt, None; P. Zanen, None; R.G.A. Ackerstaff, None.

Dialysis Access, Education/ Training Credentialing

PP20.

Early Commercialization Experience with New Long Term Vascular Access for Catheter-Dependent Patients

Howard E Katzman. University of Miami Hospital, Miami, FL

Objectives: The purpose of this abstract is to report early commercialization experience with the HeRO™ Vascular Access Device, a new long-term dialysis access device approved by FDA for "access challenged" patients i.e., catheter-dependent or patients that are poor candidates for fistulas or grafts due to venous obstruction. The HeRO™ device is designed to provide a graft-like vascular access and lower bacteremia rates than a tunneled dialysis catheter.

Methods: The HeRO™ device, a graft with central outflow designed to bypass peripheral stenosis, consists of an ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous nitinol reinforced silicone outflow catheter which exits into the right atrium via the internal jugular vein. Procedural data has been captured on 60 early commercialization patients implanted with the HeRO™ device including access and medical history and device-implant success.

Results: To-date, data has been captured on 60 patients (mean age 58.9; 43.3% male; 55.0% diabetic) with a history of 4.1 years on dialysis, a mean 5.0 previous catheters, 2.2 previous grafts, and 1.5 previous fistulas and 3.6 mean previous bacteremias (range 1-17). The HeRO™ device was successfully implanted in all subjects using a variety of interventional techniques, although 60.0% percent had evidence of hemodynamically significant central venous stenosis.

Conclusions: This data demonstrates that access-challenged patients with challenging anatomy and central venous stenosis may be eligible for an alternative long-term vascular access device offering lower bacteremia rates compared to a tunneled dialysis catheter.

Author Disclosures: H.B. Katzman, Participating in HeRO commercialization registry on behalf of Hemosphere, Inc and receiving nominal research grant to complete case report forms as investigator in registry.

PP21.

Reduction and Reconstruction of Aneurysmal Arteriovenous Fistulas: Mid-Term Results of a Novel Approach to Salvage Autogenous Dialysis Access

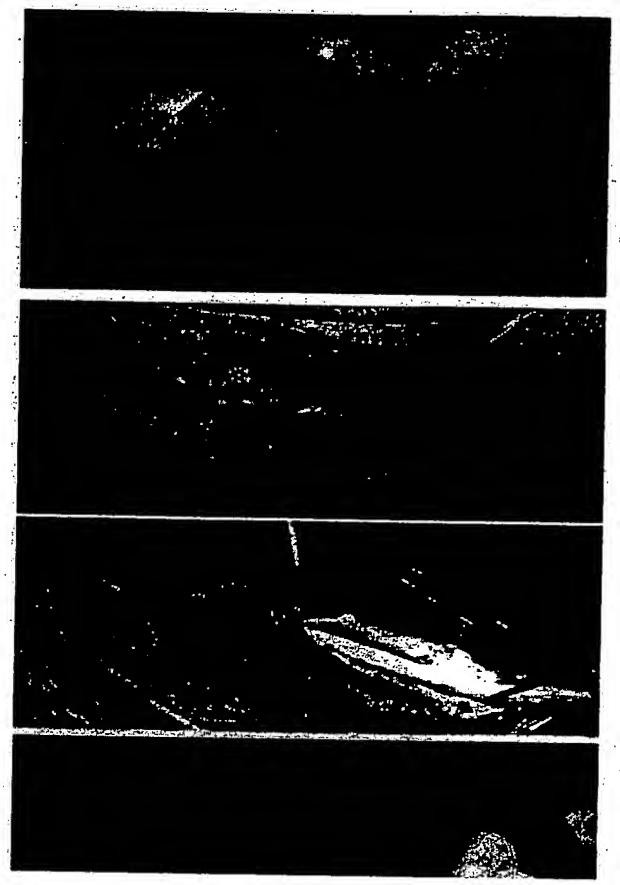
Karen Woo[1], Patrick R Cook[1], Robert J Hye[2], Timothy G Canty[2]. [1]Scripps Green Hospital, La Jolla, CA; [2]Kaiser Permanente Medical Group, San Diego, CA

Background: Over the last decade, K-DOQI guidelines have increasingly emphasized the importance of autogenous arteriovenous fistulas (AVF) for dialysis access. A complication of AVF is aneurysmal dilatation with a subset developing massive diffuse aneurysm. Treatment of massive aneurysmal AVF generally involves either ligation or resection with use of prosthetic interposition. In order to maintain an all-autogenous access, we developed a procedure to treat massive aneurysmal AVF in which the lumenal diameter is reduced, excess length is resected, and the new reconstructed AVF is retunneled for continued use.

Methods: Over a 4-year period, the reduction/revision procedure was performed on 18 patients with an AVF diameter of 4-7cm. Indications for operation were thrombosis, skin breakdown, infection, bleeding, and/or poor flow. Revision was performed by resecting redundant length, reducing diameter, and then reconstructing the fistula.

Results: Patients ranged in age from 25 to 83 with a mean of 48. There were 12 men and 6 women. The mean and median follow-up was 20 months. The mean and median primary patency was 17 and 14 months, respectively. The mean and median secondary patency was 19 and 16.5 months, respectively. Two patients died, one AVF thrombosed, and two were ligated secondary to infection. One fistula developed a stenosis that was treated with angioplasty. There are no recurrent aneurysms to date.

Conclusions: Surgical resection of excess length, reduction of lumenal diameter, and reconstruction is a viable option for the treatment of complicated massive diffusely aneurysmal AVF. This technique offers the ability to maintain the benefits of an all autogenous dialysis access while conserving future dialysis sites.



Author Disclosures: K. Woo, None; P.R. Cook, None; R.J. Hye, None; T.G. Canty, None.

PP22.

Report of the First Vascular Surgery in-Training Examination (VSITE)

Amy B Reed[1], Robert S Rhodes[2], Thomas W Biester[2], John J Ricotta[3]. [1]University of Cincinnati, Cincinnati, OH; [2]American Board of Surgery, Philadelphia, PA; [3]Washington Hospital Center, Washington, DC

Background: As Vascular surgery training has evolved from a single clinical year following general surgery training to a multi year training program with independent certification, the need for an in-training examination to assess the preparedness of the candidate for the certification process has become apparent. Our objective is to analyze the psychometric characteristics of the first Vascular Surgery In-Training Examination (VSITE) and to correlate performance on the VSITE with performance on the Qualifying Examination (QE) in Vascular Surgery.

Methods: The Vascular Surgery Board (VSB) in conjunction with the Association of Program Directors in Vascular Surgery (APDVS) appointed a panel to develop the VSITE which was administered by the Vascular Surgery Board of the American Board of Surgery(VSB/ABS). Thirty-one APDVS and SVS members contributed questions in clinical and basic science areas of vascular surgery training. All questions were again reviewed by the panel and the VSB /ABS prior to administration of the examination. The psychometric characteristics of the examination and correlation of performance on VSITE and VQE were undertaken by ABS staff.

Results: On February 16, 2008, 240 examinees took the initial Vascular Surgery In-Training Examination online through a secure, proctored website. This total included 216 vascular residents from 91 of 95 (96%) training programs. The psychometric properties of the examination were excellent with index values comparable to other ABS examinations. The average difficulty value for all items was 76.6%, the average discrimination value was 0.20, the total test reliability coefficient was 0.85 and the standard error of measurement was 2.9% correct. Scores ranged from 55% to 93% correct with an average of 76.7% correct. Sixty-four candidates took both the VSITE and the VQE in 2008. A high correlation of 0.70 was noted between

SL KHAN NAZIR

EXPANDED POLYTETRAFLUOROETHYLENE (PTFE) SUBCUTANEOUS ARTERIOVENOUS CONDUIT: AN IMPROVED VASCULAR ACCESS FOR CHRONIC HEMODIALYSIS

L. D. Baker, Jr., J. M. Johnson, and D. Goldfarb

Recent experience with expanded polytetrafluoroethylene (PTFE) has demonstrated that a specific form of this material functions extremely well as a small artery prosthesis[1]. The basic ultrastructure of expanded PTFE is illustrated in Figure 1. Spindle-shaped PTFE nodes are oriented radially in the graft wall and these nodes are interconnected by fine fibrils. This node-fibril arrangement forms a type of lattice-work, and the distance between the nodes as well as the node diameter can be varied in the fabrication process. The specific form of this material which gave the most favorable results in regards to controlled tissue ingrowth and long-term patency has the following characteristics: 1) an internodal distance of 20 to 30 μ, 2) a node diameter of less than 12 μ, 3) a wall thickness of between 0.3 and 0.5 mm, and 4) a density of 0.3 Gm/ml. Histological evaluation of these grafts revealed a thin neointima with flattened nucleated endothelial cells facing the bloodstream, along with complete and uniform transmural fibrous tissue ingrowth and intramural neocapillaries.

With the early clinical success of expanded PTFE as a femoral-popliteal artery bypass graft[2], we then considered the use of this material as a subcutaneous A-V conduit for chronic hemodialysis.

Prior to any clinical trial, however, several questions needed to be answered:

1) Could the material withstand repeated percutaneous large bore punctures?

2) Following withdrawal of the dialysis catheter would there be a reasonable and prompt cessation of bleeding?

3) Would clot propogation at the puncture site lead to obstruction of the graft?

4) Would infection of the prosthetic material become a prohibitive problem?

MATERIALS AND METHODS

Experimental. Seven grafts of expanded PTFE* were then inserted into dogs as loop fistulae between the common femoral artery and common femoral vein. Over the following 8 wks, mock dialyses were performed weekly for 4 hrs in each of these dogs with a #14 gauge Medicut catheter. These catheters were inserted percutaneously into the graft, and blood was returned to the animal through a vena puncture in the cephalic vein of the foreleg. The animals were sacrificed after the 8 wk period and the grafts examined grossly and histologically.

Clinical. From April of 1975 through February 1976, 72 patients at the Good Samaritan Hospital Kidney Center and Maricopa County General Hospital Dialysis Unit, Phoenix, Arizona, have been dialyzed using the expanded PTFE subcutaneous A-V conduit (Table I). Forty-three of these patients are male and 29 female. The ages of these patients range from 19 to 73 yrs, with a mean age of 46 yrs. Our preferred method of placement has been what we term the straight forearm graft, which is an anastomosis of the graft to the distal radial artery and to the cephalic vein near the antecubital fossa. If, however, the radial artery is not satisfactory either due to insufficient flow or prior access use, a loop fistula is constructed in the forearm between the brachial artery and cephalic vein. If access sites are not available in the upper extremities, then we have implanted these grafts in the thigh, either as a straight graft between the superficial femoral artery and common femoral vein, or as a loop fistula between the common femoral artery and common femoral vein.

TABLE I

EXPERIENCE WITH PTFE A-V FISTULAS

No. of Patients	72
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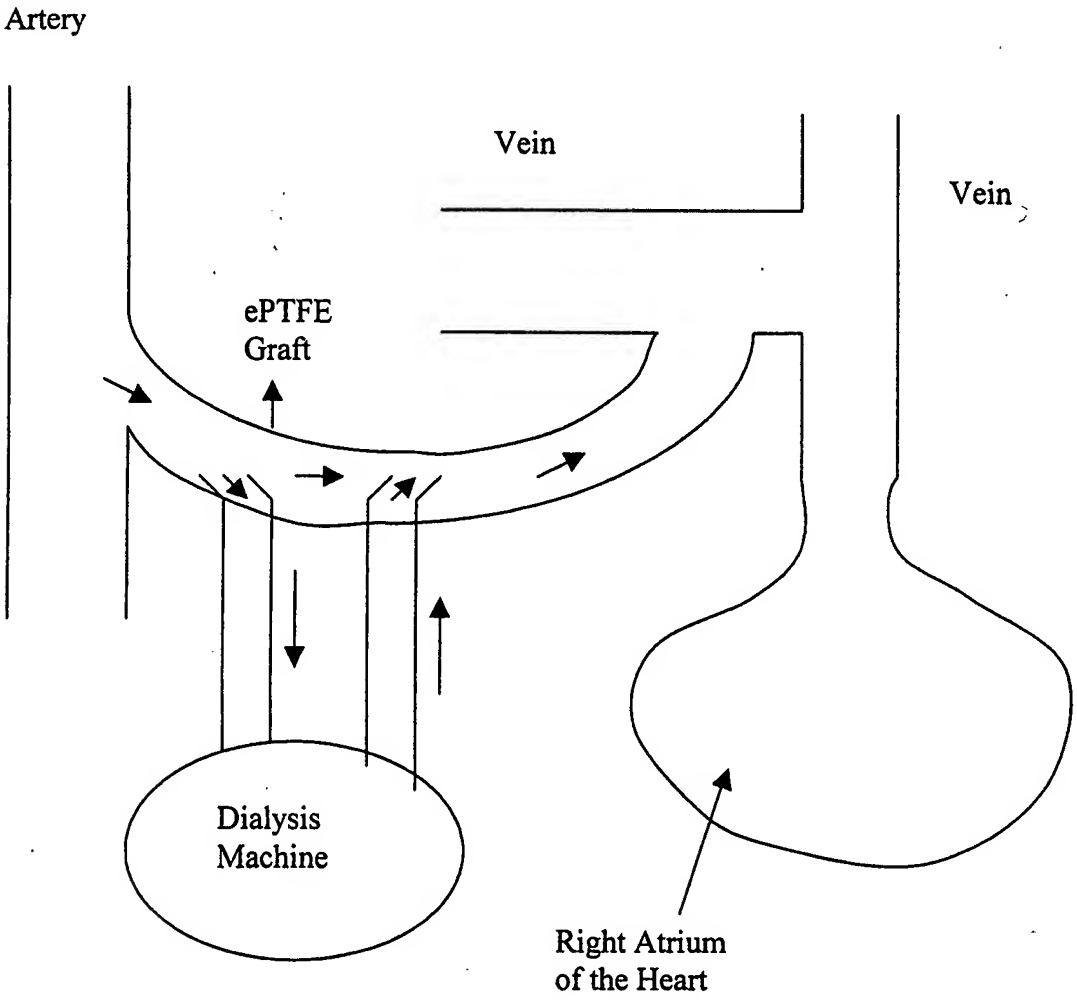
Age Distribution (yrs)	
10-19	1
20-29	11
30-39	13
40-49	13
50-59	19
60-69	11
70-79	4

We have placed a total of 84 grafts in these 72 patients with 48 in the straight forearm position, 16 as forearm loops, 6 as straight thigh grafts, 13 as thigh loops, and one as a straight arm graft, from the brachial artery at the antecubital fossa to the cephalic vein in the delto-pectoral groove. The majority of these grafts have been 8 mm in diameter, with 10 being 6 mm in diameter. Most of these grafts have been used within 3 days of implantation and several have been employed within 3 hrs. The period of observation has ranged from 4 to 50 wks.

From the Arizona State University-St. Joseph's Hospital Biomedical Engineering Research and Education Program, and Good Samaritan Hospital, Phoenix, Arizona.

Supported in part by The Robert and Irene Flinn Foundation.

*Impra graft, International Medical Prosthetic Research Associates, Inc., 4209 South 36th Place, Phoenix, Arizona.



BITTNER ARTERIOVENOUS SHUNT – (1976)
Subcutaneous with ePTFE conduit

FIG. 4

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browse before

2144.04 Legal Precedent as Source of Supporting Rationale [R-1] - 2100 Patentability

2144.04 Legal Precedent as Source of Supporting Rationale [R-1]

As discussed in MPEP § 2144, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

I. AESTHETIC DESIGN CHANGES

In re Seid, 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.). But see *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999) (The claims of a utility application, drawn to a generally round, orange plastic trash bag with a jack-o-lantern face, were rejected under 35 U.S.C. 103. However, the court reversed the rejection for lack of motivation to combine conventional trash bags with a reference showing a jack-o-lantern face on an orange paper bag stuffed with newspapers.); *Ex parte Hilton*, 148 USPQ 356 (Bd. App. 1965) (Claims were directed to fried potato chips with a specified moisture and fat content, whereas the prior art was directed to french fries having a higher moisture content. While recognizing that in some cases the particular shape of a product is of no patentable significance, the Board held in this case the shape (chips) is important because it results in a product which is distinct from the reference product (french fries).).

II. ELIMINATION OF A STEP OR AN ELEMENT AND ITS FUNCTION

A. Omission of an Element and Its Function Is Obvious If the Function of the Element Is Not Desired

Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to

establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

C. Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

V. MAKING PORTABLE, INTEGRAL, SEPARABLE, ADJUSTABLE, OR CONTINUOUS

A. Making Portable

In re Lindberg, 194 F.2d 732, 93 USPQ 23 (CCPA 1952) (Fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results.).

B. Making Integral

In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); but see *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." Nortron argued that the invention is just making integral what had been made in four bolted pieces.

in Re Leonard R. Kahn., 441 F.3d 977 (Fed. Cir. 2006)

Federal Circuits, Fed. Cir. (March 22, 2006)

Docket number: 04-1616

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U.S. Supreme Court

GRAHAM v. JOHN DEERE CO., 383 U.S. 1 (1966)

383 U.S. 1

GRAHAM ET AL. v. JOHN DEERE CO. OF KANSAS CITY ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT.
No. 11.
Argued October 14, 1965.
Decided February 21, 1966. *

[Footnote *] Together with No. 37, Calmar, Inc. v. Cook Chemical Co., and No. 43, Colgate-Palmolive Co. v. Cook Chemical Co., also on certiorari to the same court.

In No. 11 petitioners sued for infringement of a patent, consisting of a combination of old mechanical elements, for a device designed to absorb shock from plow shanks in rocky soil to prevent damage to the plow. In 1955 the Fifth Circuit held the patent valid, ruling that a combination is patentable when it produces an "old result in a cheaper and otherwise more advantageous way." Here the Eighth Circuit held that since there was no new result in the combination the patent was invalid. Petitioners in Nos. 37 and 43 filed actions for declaratory judgments declaring invalid respondent's patent relating to a plastic finger sprayer with a "hold-down" cap used as a built-in dispenser for containers with liquids, principally insecticides. By cross-action respondent claimed infringement. The District Court and the Court of Appeals sustained the patent. Held: The patents do not meet the test of the "nonobvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the pertinent art, set forth in 103 of the Patent Act of 1952, and are therefore invalid. Pp. 3-37. [383 U.S. 1, 2]

(a) In carrying out the constitutional command of Art. I, 8, that a patent system "promote the Progress of . . . useful Arts," Congress established the two statutory requirements of novelty and utility in the Patent Act of 1793. Pp. 3, 6, 12.

(b) This Court in Hotchkiss v. Greenwood, 11 How. 248 (1851), additionally conditioned the issuance of a patent upon the evidence of more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business. P. 11.

(c) In 103 of the 1952 Patent Act Congress added the statutory nonobvious subject matter requirement, originally expounded in Hotchkiss, which merely codified judicial precedents requiring a comparison of the subject matter sought to be patented and the prior art, tying patentable inventions to advances in the art. Although 103 places emphasis upon inquiries into obviousness, rather than into "invention," the general level of innovation necessary to sustain patentability remains unchanged under the 1952 Act. Pp. 14-17.

(d) This section permits a more practical test of patentability. The determination of "nonobviousness" is made after establishing the scope and content of prior art, the differences between the prior art and the claims at issue; and the level of ordinary skill in the pertinent art. P. 17.

(e) With respect to each patent involved here the differences between the claims in issue and the pertinent prior art would have been obvious to a person reasonably skilled in that art. Pp. 25-26, 37.

333 F.2d 529, affirmed; 336 F.2d 110, reversed and remanded.

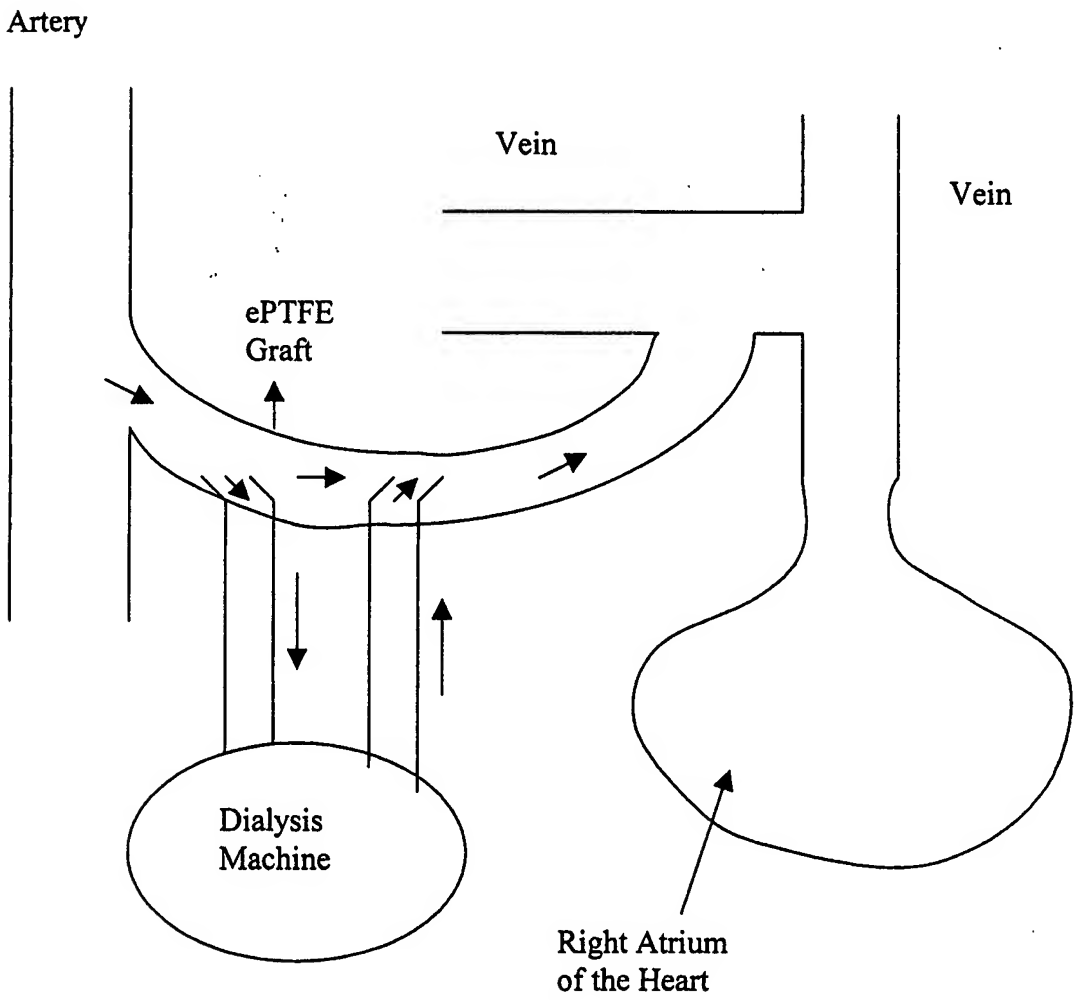

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FIG. 4

S KHAN NAZIR

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Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

KSR INTERNATIONAL CO. *v.* TELEFLEX INC. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 04–1350. Argued November 28, 2006—Decided April 30, 2007

To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be taken off the shelf and attached to any

Syllabus

mechanical pedal to allow it to function with a computer-controlled throttle. The '068 patent disclosed one such sensor. Chevrolet also manufactured trucks using modular sensors attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates. Other patents disclose electronic sensors attached to adjustable pedal assemblies. For example, the Rixon patent locates the sensor in the pedal footpad, but is known for wire chafing.

After petitioner KSR developed an adjustable pedal system for cars with cable-actuated throttles and obtained its '976 patent for the design, General Motors Corporation (GMC) chose KSR to supply adjustable pedal systems for trucks using computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR added a modular sensor to its design. Respondents (Teleflex) hold the exclusive license for the Engelgau patent, claim 4 of which discloses a position-adjustable pedal assembly with an electronic pedal position sensor attached a fixed pivot point. Despite having denied a similar, broader claim, the U. S. Patent and Trademark Office (PTO) had allowed claim 4 because it included the limitation of a fixed pivot position, which distinguished the design from Redding's. Asano was neither included among the Engelgau patent's prior art references nor mentioned in the patent's prosecution, and the PTO did not have before it an adjustable pedal with a fixed pivot point. After learning of KSR's design for GMC, Teleflex sued for infringement, asserting that KSR's pedal system infringed the Engelgau patent's claim 4. KSR countered that claim 4 was invalid under §103 of the Patent Act, which forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."

Graham v. *John Deere Co. of Kansas City*, 383 U. S. 1, 17–18, set out an objective analysis for applying §103: "[T]he scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." While the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry. However, seeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a "teaching, suggestion, or motivation" (TSM) test, under which a pat-

ent claim is only proved obvious if the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings.

The District Court granted KSR summary judgment. After reviewing pedal design history, the Engelgau patent's scope, and the relevant prior art, the court considered claim 4's validity, applying *Graham*'s framework to determine whether under summary-judgment standards KSR had demonstrated that claim 4 was obvious. The court found "little difference" between the prior art's teachings and claim 4: Asano taught everything contained in the claim except using a sensor to detect the pedal's position and transmit it to a computer controlling the throttle. That additional aspect was revealed in, *e.g.*, the '068 patent and Chevrolet's sensors. The court then held that KSR satisfied the TSM test, reasoning (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to Rixon's chafing problems by positioning the sensor on the pedal's fixed structure, which could lead to the combination of a pedal like Asano with a pedal position sensor.

Reversing, the Federal Circuit ruled the District Court had not applied the TSM test strictly enough, having failed to make findings as to the specific understanding or principle within a skilled artisan's knowledge that would have motivated one with no knowledge of the invention to attach an electronic control to the Asano assembly's support bracket. The Court of Appeals held that the District Court's recourse to the nature of the problem to be solved was insufficient because, unless the prior art references addressed the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references. The appeals court found that the Asano pedal was designed to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted, whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. The Rixon pedal, said the court, suffered from chafing but was not designed to solve that problem and taught nothing helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not necessarily go to the issue of motivation to attach the electronic control on the pedal assembly's support bracket. So interpreted, the court held, the patents would not have led a person of ordinary skill to put a sensor on an Asano-like pedal. That it might have been obvious to try that combination was likewise irrelevant. Finally, the court held that genuine issues of material fact precluded summary judgment.

Held: The Federal Circuit addressed the obviousness question in a narrow, rigid manner that is inconsistent with §103 and this Court's

precedents. KSR provided convincing evidence that mounting an available sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art and that the benefit of doing so would be obvious. Its arguments, and the record, demonstrate that the Engelgau patent's claim 4 is obvious. Pp. 11–24.

1. *Graham* provided an expansive and flexible approach to the obviousness question that is inconsistent with the way the Federal Circuit applied its TSM test here. Neither §103's enactment nor *Graham*'s analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. See *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U. S. 147, 152. Such a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See, *e.g.*, *United States* v. *Adams*, 383 U. S. 39, 50–52. When a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability. Moreover, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions. Following these principles may be difficult if the claimed subject matter involves more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ. Pp. 11–14.

(b) The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as

innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. Helpful insights, however, need not become rigid and mandatory formulas. If it is so applied, the TSM test is incompatible with this Court's precedents. The diversity of inventive pursuits and of modern technology counsels against confining the obviousness analysis by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasizing the importance of published articles and the explicit content of issued patents. In many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility. Since the TSM test was devised, the Federal Circuit doubtless has applied it in accord with these principles in many cases. There is no necessary inconsistency between the test and the *Graham* analysis. But a court errs where, as here, it transforms general principle into a rigid rule limiting the obviousness inquiry. Pp. 14–15.

(c) The flaws in the Federal Circuit's analysis relate mostly to its narrow conception of the obviousness inquiry consequent in its application of the TSM test. The Circuit first erred in holding that courts and patent examiners should look only to the problem the patentee was trying to solve. Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed. Second, the appeals court erred in assuming that a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem. The court wrongly concluded that because Asano's primary purpose was solving the constant ratio problem, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, it provided an obvious example of an adjustable pedal with a fixed pivot point, and the prior art was replete with patents indicating that such a point was an ideal mount for a sensor. Third, the

court erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Finally, the court drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law. Pp. 15–18.

2. Application of the foregoing standards demonstrates that claim 4 is obvious. Pp. 18–23.

(a) The Court rejects Teleflex's argument that the Asano pivot mechanism's design prevents its combination with a sensor in the manner claim 4 describes. This argument was not raised before the District Court, and it is unclear whether it was raised before the Federal Circuit. Given the significance of the District Court's finding that combining Asano with a pivot-mounted pedal position sensor fell within claim 4's scope, it is apparent that Teleflex would have made clearer challenges if it intended to preserve this claim. Its failure to clearly raise the argument, and the appeals court's silence on the issue, lead this Court to accept the District Court's conclusion. Pp. 18–20.

(b) The District Court correctly concluded that when Engelgau designed the claim 4 subject matter, it was obvious to a person of ordinary skill in the art to combine Asano with a pivot-mounted pedal position sensor. There then was a marketplace creating a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The Federal Circuit considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet trucks and disclosed in the '068 patent. The proper question was whether a pedal designer of ordinary skill in the art, facing the wide range of needs created by developments in the field, would have seen an obvious benefit to upgrading Asano with a sensor. For such a designer starting with Asano, the question was where to attach the sensor. The '936 patent taught the utility of putting the sensor on the pedal device. Smith, in turn, explained not to put the sensor on the pedal footpad, but instead on the structure. And from Rixon's known wire-chafing problems, and Smith's teaching that the pedal assemblies must not precipitate any motion in the connecting wires,

Syllabus

the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious such point is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor there. Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Teleflex has not shown anything in the prior art that taught away from the use of Asano, nor any secondary factors to dislodge the determination that claim 4 is obvious. Pp. 20–23.

3. The Court disagrees with the Federal Circuit's holding that genuine issues of material fact precluded summary judgment. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U. S., at 17. Where, as here, the prior art's content, the patent claim's scope, and the level of ordinary skill in the art are not in material dispute and the claim's obviousness is apparent, summary judgment is appropriate. P. 23.

119 Fed. Appx. 282, reversed and remanded.

KENNEDY, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 04–1350

KSR INTERNATIONAL CO., PETITIONER *v.*
TELEFLEX INC. ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[April 30, 2007]

JUSTICE KENNEDY delivered the opinion of the Court.

Teleflex Incorporated and its subsidiary Technology Holding Company—both referred to here as Teleflex—sued KSR International Company for patent infringement. The patent at issue, United States Patent No. 6,237,565 B1, is entitled "Adjustable Pedal Assembly With Electronic Throttle Control." Supplemental App. 1. The patentee is Steven J. Engelgau, and the patent is referred to as "the Engelgau patent." Teleflex holds the exclusive license to the patent.

Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine. When Teleflex accused KSR of infringing the Engelgau patent by adding an electronic sensor to one of KSR's previously designed pedals, KSR countered that claim 4 was invalid under the Patent Act, 35 U. S. C. §103, because its subject matter was obvious.

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be pat-

ented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

In *Graham* v. *John Deere Co. of Kansas City*, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss* v. *Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:

> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.*, at 17–18.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under §103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the "teaching, suggestion, or motivation" test (TSM test), under which a patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teachings" can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. See, *e.g.*, *Al-Site Corp.* v. *VSI*

Int'l, Inc., 174 F. 3d 1308, 1323–1324 (CA Fed. 1999). KSR challenges that test, or at least its application in this case. See 119 Fed. Appx. 282, 286–290 (CA Fed. 2005). Because the Court of Appeals addressed the question of obviousness in a manner contrary to §103 and our precedents, we granted certiorari, 547 U. S ___ (2006). We now reverse.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cable-actuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990's it became more common to install computers in cars to control engine operation. Computer-controlled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate adjustments of air and fuel mixture are possible. The computer's rapid processing of factors beyond the pedal's position improves fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver's operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the me-

chanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U. S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061 (filed Sept. 17, 1993) (Redding). The Asano patent reveals a support structure that houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engelgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U. S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. U. S. Patent No. 5,063,811 (filed July 9, 1990) (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U. S. Patent No. 5,385,068 (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors "attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation." 298 F. Supp. 2d 581, 589 (ED Mich. 2003).

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U. S. Patent No. 5,819,593 (filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads to the instant case.

B

KSR, a Canadian company, manufactures and supplies auto parts, including pedal systems. Ford Motor Company hired KSR in 1998 to supply an adjustable pedal system for various lines of automobiles with cable-actuated throttle controls. KSR developed an adjustable mechanical pedal for Ford and obtained U. S. Patent No. 6,151,976 (filed July 16, 1999) ('976) for the design. In 2000, KSR was chosen by General Motors Corporation (GMC or GM) to supply adjustable pedal systems for Chevrolet and GMC light trucks that used engines with computer-controlled throttles. To make the '976 pedal compatible with the

trucks, KSR merely took that design and added a modular sensor.

Teleflex is a rival to KSR in the design and manufacture of adjustable pedals. As noted, it is the exclusive licensee of the Engelgau patent. Engelgau filed the patent application on August 22, 2000 as a continuation of a previous application for U. S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Engelgau, col. 2, lines 2–5, Supplemental App. 6. Claim 4 of the patent, at issue here, describes:

> "A vehicle control pedal apparatus comprising:
>
> a support adapted to be mounted to a vehicle structure;
>
> an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support;
>
> a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and
>
> an electronic control attached to said support for controlling a vehicle system;
>
> said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot." *Id.*, col.

6, lines 17–36, Supplemental App. 8 (diagram numbers omitted).

We agree with the District Court that the claim discloses "a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal." 298 F. Supp. 2d, at 586–587.

Before issuing the Engelgau patent the U. S. Patent and Trademark Office (PTO) rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

> "'Since the prior ar[t] references are from the field of endeavor, the purpose disclosed . . . would have been recognized in the pertinent art of Redding. Therefore it would have been obvious . . . to provide the device of Redding with the . . . means attached to a support member as taught by Smith.'" *Id.*, at 595.

In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal's support structure, and the rejected patent claim merely put these two teachings together.

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding's. *Ibid.* Engelgau had not included Asano among the prior art references, and Asano was not mentioned in the patent's prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

Upon learning of KSR's design for GM, Teleflex sent a

warning letter informing KSR that its proposal would violate the Engelgau patent. "'Teleflex believes that any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs technology covered by one or more'" of Teleflex's patents. *Id.*, at 585. KSR refused to enter a royalty arrangement with Teleflex; so Teleflex sued for infringement, asserting KSR's pedal infringed the Engelgau patent and two other patents. *Ibid.* Teleflex later abandoned its claims regarding the other patents and dedicated the patents to the public. The remaining contention was that KSR's pedal system for GM infringed claim 4 of the Engelgau patent. Teleflex has not argued that the other three claims of the patent are infringed by KSR's pedal, nor has Teleflex argued that the mechanical adjustable pedal designed by KSR for Ford infringed any of its patents.

C

The District Court granted summary judgment in KSR's favor. After reviewing the pertinent history of pedal design, the scope of the Engelgau patent, and the relevant prior art, the court considered the validity of the contested claim. By direction of 35 U. S. C. §282, an issued patent is presumed valid. The District Court applied *Graham*'s framework to determine whether under summary-judgment standards KSR had overcome the presumption and demonstrated that claim 4 was obvious in light of the prior art in existence when the claimed subject matter was invented. See §102(a).

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was "'an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles.'" 298 F. Supp. 2d, at 590. The court then set forth the relevant prior art, in-

cluding the patents and pedal designs described above.

Following *Graham*'s direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." 298 F. Supp. 2d, at 590. Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion. The District Court granted summary judgment for KSR.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been strict enough in applying the test, having failed to make "'finding[s] as to the specific understanding or principle

within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention' . . . to attach an electronic control to the support bracket of the Asano assembly." 119 Fed. Appx., at 288 (brackets in original) (quoting *In re Kotzab*, 217 F. 3d 1365, 1371 (CA Fed. 2000)). The Court of Appeals held that the District Court was incorrect that the nature of the problem to be solved satisfied this requirement because unless the "prior art references address[ed] the precise problem that the patentee was trying to solve," the problem would not motivate an inventor to look at those references. 119 Fed. Appx., at 288.

Here, the Court of Appeals found, the Asano pedal was designed to solve the "'constant ratio problem'"—that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted—whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. *Ibid.* As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court's view Rixon did not teach anything helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not "necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly." *Ibid.* When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano.

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because "'"[o]bvious to try" has long been held not to constitute obviousness.'" *Id.*, at 289 (quoting *In re Deuel*, 51 F. 3d 1552, 1559 (CA Fed. 1995)).

The Court of Appeals also faulted the District Court's consideration of the PTO's rejection of the broader version of claim 4. The District Court's role, the Court of Appeals

explained, was not to speculate regarding what the PTO might have done had the Engelgau patent mentioned Asano. Rather, the court held, the District Court was obliged first to presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art. The fact that the PTO had rejected the broader version of claim 4, the Court of Appeals said, had no place in that analysis.

The Court of Appeals further held that genuine issues of material fact precluded summary judgment. Teleflex had proffered statements from one expert that claim 4 "'was a simple, elegant, and novel combination of features,'" 119 Fed. Appx., at 290, compared to Rixon, and from another expert that claim 4 was nonobvious because, unlike in Rixon, the sensor was mounted on the support bracket rather than the pedal itself. This evidence, the court concluded, sufficed to require a trial.

II

A

We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for "uniformity and definiteness." 383 U. S., at 18. Yet the principles laid down in *Graham* reaffirmed the "functional approach" of *Hotchkiss*, 11 How. 248. See 383 U. S., at 12. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.

Neither the enactment of §103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a

half century, the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States* v. *Adams*, 383 U. S. 39, 40 (1966), a companion case to *Graham*, the Court considered the obviousness of a "wet battery" that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U. S., at 50–51. It nevertheless rejected the Government's claim that Adams's battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51–52. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.

In *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U. S. 57 (1969), the Court elaborated on this approach.

The subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60–62. In those circumstances, "while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented," and the patent failed under §103. *Id.*, at 62 (footnote omitted).

Finally, in *Sakraida* v. *AG Pro, Inc.*, 425 U. S. 273 (1976), the Court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious. *Id.*, at 282.

The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Following these principles may be more difficult in other

cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

B

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See *Application of Bergel,* 292 F. 2d 955, 956–957 (1961). As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established

functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

C

The flaws in the analysis of the Court of Appeals relate

for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under §103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. 119 Fed. Appx., at 288. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. *Ibid.* The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. *Ibid.* Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a

puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co.* v. *Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964))). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

We note the Court of Appeals has since elaborated a

broader conception of the TSM test than was applied in the instant matter. See, *e.g., DyStar Textilfarben GmbH & Co. Deutschland KG* v. *C. H. Patrick Co.*, 464 F. 3d 1356, 1367 (2006) ("Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense"); *Alza Corp.* v. *Mylan Labs., Inc.*, 464 F. 3d 1286, 1291 (2006) ("There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine . . ."). Those decisions, of course, are not now before us and do not correct the errors of law made by the Court of Appeals in this case. The extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases. What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.

III

When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court's recitation of the relevant prior art and its determination of the level of ordinary skill in the field. As did the District Court, we see little difference between the teachings of Asano and Smith and the adjustable electronic pedal disclosed in claim 4 of the Engelgau patent. A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.

A

Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by

claim 4 because of the design of Asano's pivot mechanisms. See Brief for Respondents 48–49, and n. 17. Therefore, Teleflex reasons, even if adding a sensor to Asano was obvious, that does not establish that claim 4 encompasses obvious subject matter. This argument was not, however, raised before the District Court. There Teleflex was content to assert only that the problem motivating the invention claimed by the Engelgau patent would not lead to the solution of combining of Asano with a sensor. See Teleflex's Response to KSR's Motion for Summary Judgment of Invalidity in No. 02–74586 (ED Mich.), pp. 18–20, App. 144a–146a. It is also unclear whether the current argument was raised before the Court of Appeals, where Teleflex advanced the nonspecific, conclusory contention that combining Asano with a sensor would not satisfy the limitations of claim 4. See Brief for Plaintiffs-Appellants in No. 04–1152 (CA Fed.), pp. 42–44. Teleflex's own expert declarations, moreover, do not support the point Teleflex now raises. See Declaration of Clark J. Radcliffe, Ph.D., Supplemental App. 204–207; Declaration of Timothy L. Andresen, *id.*, at 208–210. The only statement in either declaration that might bear on the argument is found in the Radcliffe declaration:

> "Asano . . . and Rixon . . . are complex mechanical linkage-based devices that are expensive to produce and assemble and difficult to package. It is exactly these difficulties with prior art designs that [Engelgau] resolves. The use of an adjustable pedal with a single pivot reflecting pedal position combined with an electronic control mounted between the support and the adjustment assembly at that pivot was a simple, elegant, and novel combination of features in the Engelgau '565 patent." *Id.*, at 206, ¶16.

Read in the context of the declaration as a whole this is best interpreted to mean that Asano could not be used to

solve "[t]he problem addressed by Engelgau '565[:] to provide a less expensive, more quickly assembled, and smaller package adjustable pedal assembly with electronic control." *Id.*, at 205, ¶10.

The District Court found that combining Asano with a pivot-mounted pedal position sensor fell within the scope of claim 4. 298 F. Supp. 2d, at 592–593. Given the sigificance of that finding to the District Court's judgment, it is apparent that Teleflex would have made clearer challenges to it if it intended to preserve this claim. In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct.

B

The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The District Court employed this narrow inquiry as well, though it reached the correct result nevertheless. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one

component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," Smith, col. 1, lines 35–37, Supplemental App. 274, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to

those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Teleflex indirectly argues that the prior art taught away from attaching a sensor to Asano because Asano in its view is bulky, complex, and expensive. The only evidence Teleflex marshals in support of this argument, however, is the Radcliffe declaration, which merely indicates that Asano would not have solved Engelgau's goal of making a small, simple, and inexpensive pedal. What the declaration does not indicate is that Asano was somehow so flawed that there was no reason to upgrade it, or pedals like it, to be compatible with modern engines. Indeed, Teleflex's own declarations refute this conclusion. Dr. Radcliffe states that Rixon suffered from the same bulk and complexity as did Asano. See *id.*, at 206. Teleflex's other expert, however, explained that Rixon was itself designed by adding a sensor to a pre-existing mechanical pedal. See *id.*, at 209. If Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either. Teleflex may have made a plausible argument that Asano is inefficient as compared to Engelgau's preferred embodiment, but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided. Accordingly, Teleflex has not shown anything in the prior art that taught away from the use of Asano.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of *Graham* and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of §103.

We need not reach the question whether the failure to

disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.

IV

A separate ground the Court of Appeals gave for reversing the order for summary judgment was the existence of a dispute over an issue of material fact. We disagree with the Court of Appeals on this point as well. To the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays in the analysis. In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U. S., at 17. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

* * *

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our

shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U. S. Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in §103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

KSR provided convincing evidence that mounting a modular sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. Its arguments, and the record, demonstrate that claim 4 of the Engelgau patent is obvious. In rejecting the District Court's rulings, the Court of Appeals analyzed the issue in a narrow, rigid manner inconsistent with §103 and our precedents. The judgment of the Court of Appeals is reversed, and the case remanded for further proceedings consistent with this opinion.

It is so ordered.

702 F2d 989 In Re Howard Sernaker

702 F.2d 989

217 U.S.P.Q. 1

In re Howard SERNAKER.

Appeal No. 82-579.
Serial No. 916,018.

United States Court of Appeals,
Federal Circuit.

Feb. 28, 1983.

Michael F. Petock, Philadelphia, Pa., argued and filed briefs for appellant.

Associate Sol. Fred W. Sherling, Washington, D.C., argued for Patent and Trademark Office. With him on th Sol., Joseph F. Nakamura, Washington, D.C.

Before DAVIS, Circuit Judge, COWEN, Senior Circuit Judge, and NICHOLS, Circuit Judge.

NICHOLS, Circuit Judge.

1

This case is before us on appeal from the decision of the Patent and Trademark Office Board of Appeals (boa decision, the board affirmed the examiner's rejection, under 35 U.S.C. Sec. 103, of claims 1-6 and 8-11 in a application serial No. 916,018, filed June 15, 1978, entitled "Embroidered Transfer and Method of Making." comprise all the claims in the case. We reverse.

2

* Background

A. The Invention

3

Appellant has invented a type of embroidered emblem and a method of making the same. Claims 1 and 10, independent claims in appellant's application, are representative of the method and of the emblem, respect

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1. A method of making an embroidered transfer or emblem comprising the steps of:

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(a) embroidering a pattern on a portion of a substrate while using thread free from oil and with said thread single color and in an amount so that a portion of the pattern is sculptured by having a greater thickness th portion of the pattern,

6

(b) separating the pattern and its associated substrate portion from the remainder of the substrate,

7

(c) providing a transfer print on paper with a dyestuff of at least two different colors and capable of sublimi and pressure or vacuum,

8

(d) registering portions of the print with mating portion of said pattern,

9

(e) transferring color from said print as a gas to the warp side of the pattern while applying sufficient heat t dyestuff.

10

10. An embroidered transfer emblem comprising an embroidered pattern on one side of a substrate whose s corresponds to the size of the pattern with thread of a single color which is free of needle oil, portions of th having a sculptured effect by an increased number of thread stitches, at least two colors of dyestuff printed stitches defining said portions and on other portions of the pattern, said colors being in registry with said sc portions of said pattern with at least one of said printed portions including printing outlining a configuration of said pattern, and said colors being printed on the warp side of said pattern.

11

The remaining claims are either dependent on method claim 1 (claims 2-6) or on article claim 10 (claims 8, For example, claim 2 defines a method in accordance with claim 1 of "applying a thermoplastic adhesive to side of the thusly printed pattern." Since neither of the parties argue separately the patentability of each of claims, the dependent claims will stand or fall with independent claims 1 and 10. In re Burckel, 592 F.2d 11 201 U.S.P.Q. 67, 70 (Cust. & Pat.App.1979).

12

The claim language includes several key phrases that we should define at the outset. When the inventor us "registering" and "in registry," he appears by the context to mean placing or placed in correspondence. A "s literally means a basis on which an organism lives, as a plant on the soil. Another common definition of the scientific circles is any solid surface on which a coating or layer of different material is deposited. Under bot application to an embroidery is an understandable analogy.

13

The record includes samples of the "emblems" made by the claimed method, as completed, and in intermec As completed, the "emblems" are justly characterized by the board as "extremely attractive." They are appa affixed to garments to convey messages about the loyalties, affiliations, tastes, and preferences of the wea that we judges had something of the sort to brighten up our robes!

14

The emblem produced by appellant's method resembles an emblem initially embroidered with different colo Appellant's method, however, circumvents the need to embroider the desired pattern with these different c threads. Rather, a manufacturer following appellant's method first embroiders the pattern with thread of on substrate, separates the embroidery and its associated substrate from the rest of the substrate, and then e the threads different colors by use of a transfer print. Such a transfer print consists of two or more dyestuff paper arranged in a pattern mirroring in shape or "mating" the pattern of the embroidery. By placing the tr over the embroidery so that the dyestuffs face the embroidery and match its pattern, and then by applying pressure or vacuum conditions, the dyestuffs on the paper will sublime and then adhere to the matching po embroidery.

15

Before appellant's invention, a manufacturer would use the Schiffli embroidery machine alone to mass prod embroidery. This large machine, however, cannot stitch thread of more than one color at a time. Thus, to c multicolored patterns, the machine would be shut down after each separate color had been embroidered so needles could be rethreaded with the next color thread. Since each rethreading procedure takes about 45 m number of different colors that were commercially feasible to use in a single emblem was limited. With appe invented method, on the other hand, a manufacturer can produce an emblem of many colors because he n rethread the machine anew for each desired color. Instead, only one color (usually white) is used for the en embroidered pattern, and then the pattern is dyed different colors with one multicolored transfer print.

B. The References

16

The references relied upon by the board are:

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Haigh	3,657,060	April 18, 1972
Cox	3,974,010	August 10, 1976
Sernaker	4,092,451	May 30, 1978
British patent	1,243,223	August 18, 1971

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Miles, L.W.C., Journal of the Society of Dyers and Colorists, May 1977, pages 161-163.

19

Vellins, British Knitting Industry, Vol. 46, No. 524, January 1973, pages 45, 46, 48, 50, 53, 55, 57, 59, 63, 69.

20

The Butterick Fabric Handbook, Published by Butterick Publishing, A Division of American Can Company, Ne York, 1975, pages 99, 100, 119-121, and 142.

21

The British patent discloses a process of transfer printing on all types of textile articles regardless of their fi like process of printing on a variety of non-textile articles. With respect to transfer printing on textile article patent recites a general line of materials to which the process may be applied:

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* * * [F]leeces or webs of non-woven fibers, textile threads, woven webs, knitted material, lace, spongy m form or already shaped, or even made up articles of clothing.

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[British, page 1, lines 68-72.]

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The British patent does not specifically mention embroidery as an article susceptible to transfer printing. Th does, however, teach that a multicolored design may be transferred to textile articles, generally, from a tra

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* * * [S]everal dyes of different colours can be applied on the same support [of the transfer print], these d either intimately mixed or distributed in order to form the designs which are to be transferred to the textile

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[British, page 2, lines 44-48, emphasis supplied.]

27

The Miles reference teaches that transfer printing can be done on a variety of substrates, such as substrate and of carpet tile. Miles specifically states that when transferring designs from a paper transfer print to fibe contact is not necessary because of the vapor state of the dye when it transfers. Although Miles exhibits an embroidery procedures, he does so in the context of describing the transfer of embroidered patterns onto nonembroidered surfaces; Miles does not teach transfer printing on embroidery itself. Vellins not only teach printing on a variety of textile substrates (including carpet), but also teaches the deleterious effects of trans on a polyester substrate that contains lubricating oil and other such substances.

28

The remainder of the references concern various embroidery techniques and methods of producing embroid emblems, rather than teachings about transfer printing. Butterick reveals that white-on-white embroidery, embroidery decoration on a white tablecloth, is commonly made. Butterick also teaches that designs formed be outlined with embroidery stitching; Butterick defines this entire piece of lace as "re-embroidered lace."

29

The Haigh patent discloses an embroidered emblem comprised of an embroidered design stitched onto a wo backing material with an embroidered border, and a thermoplastic adhesive bonded to the other side of the material.

30

The Cox patent discloses a method of preparing articles of "aetzed" embroidery whereby a design is embroi onto a backing of thermoplastic material, the design and backing are ironed onto a transfer strip, and then strip is removed taking with it all parts of the backing not in contact with the embroidery. Embroidery is "ae heat is used to remove the portions of a backing not in contact with embroidery stitches, so that the embro is left hanging together like lace. The portions of the thermoplastic backing that remain in contact with the become absorbed or melted into the embroidery as a result of the ironing and serve to improve the bondinç embroidery stitches and to give the embroidery more body. This improved bonding eliminates the need for interlock stitches, which would otherwise provide such additional bonding.

31

The Sernaker patent, issued to appellant in this case, discloses an embroidered transfer wherein a pattern i onto one side of a diaphanous material with the Schiffli machine, and a layer of adhesive is applied to the o this material. When this transfer is ironed onto a base fabric, the diaphanous material melts into the fabric disappears from view; the transfer thus assumes the appearance of a pattern that is directly embroidered o fabric.

C. The Rejection

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The board affirmed the examiner's rejection of claims 1, 4-6, and 9-111 under 35 U.S.C. Sec. 103 as obviou British taken with Miles, Vellins, and Butterick. The board also affirmed the rejection of claims 2, 3, and 8 fc reasons and further in view of Cox or Haigh and Sernaker. The board took the position that appellant's inve essence consisted of two known elements or procedures: (1) the transfer printing of multicolored designs fr strip onto various types of substrates, including fabrics, and (2) the making of embroidered transfers or em stitching a pattern of different colored threads onto a substrate.

33

After noting that appellant had admitted that both of these elements were known in the prior art, the board the manner in which appellant combined them to make a novel article in the following way: "A substrate is single colored or white thread and then dyed in the form of a design by transfer printing." Transcript at 75. subsequent analysis of the cited references, the board treated various aspects of the appellant's claims as e by the references concerning transfer printing or those concerning emblem-making. The board thus reduce to the question "whether it would have been obvious for one skilled in this art, having these references avai the dye transfer process for coloring embroidered emblems." Transcript at 75. The board answered affirmat

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After reviewing the references, we come to the conclusion that the dye transfer process has been taught to almost any type of substrate, from relatively smooth fabrics to materials, such as carpets, which are rough even to aluminum substrates. The formation of embroidered fabrics is known and, as is taught by Butterick, white embroidery is commonly made. We believe that one skilled in this art would readily understand that t transfer process, as described in these references, and which is acknowledged to be old by appellant, may t transfer dye in the form of a pattern to any substrate, whether smooth or rough.

35

While we find the embroidered emblems extremely attractive, we believe that the process would have been view of the cited art and that only the expected additive results are obtained. Also, we must not lose sight c the claims are generic in nature and are not limited to the specific exhibits presented in this case. We must claims with the methods and articles described in the references. When we do so, we come to the conclusio claimed process and resulting article would have been obvious to one skilled in this art.

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[Transcript at 75-76.]

II

OPINION

37

A. Whether the board correctly deduced obviousness from the prior art.

38

We may assume, for purposes of this decision, that all the prior art references in this case are sufficiently re another and to a related and common art, that the hypothetical person skilled in the art must be presumed with all of them. That being so, the next questions are (a) whether a combination of the teachings of all or a references would have suggested (expressly or by implication) the possibility of achieving further improvem combining such teachings along the line of the invention in suit, and (b) whether the claimed invention achi than a combination which any or all of the prior art references suggested, expressly or by reasonable implic manifestly related tests are indicated as appropriate by the following decisions of the former Court of Custo Appeals reviewing, as we do here, decisions of the board denying patentability under Sec. 103 on obviousn

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Cases reversing the board and holding the invention patentable--

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In re Rinehart, 531 F.2d 1048, 189 U.S.P.Q. 143 (Cust. & Pat.App.1976).

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In re Imperato, 486 F.2d 585, 179 U.S.P.Q. 730 (Cust. & Pat.App.1973).

42

In re Adams, 356 F.2d 998, 53 Cust. & Pat.App. 996, 148 U.S.P.Q. 742 (Cust. & Pat.App.1966).

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Cases affirming the board and holding the invention unpatentable for obviousness--

44

In re McLaughlin, 443 F.2d 1392, 170 U.S.P.Q. 209 (Cust. & Pat.App.1971).

45

In re Conrad, 439 F.2d 201, 169 U.S.P.Q. 170 (Cust. & Pat.App.1971).

46

In re Sheckler, 438 F.2d 999, 168 U.S.P.Q. 716 (Cust. & Pat.App.1971).

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And there are many others. All these cases are binding precedents in this tribunal, as much as our own will Corp. v. United States, 690 F.2d 1368 (Fed.Cir.1982). None can be treated as discredited merely because e them can be taken out of their context and construed as in conflict with expressions in other cases. Some m prefer the results of the first trio, others of the second. The tests stated above, (a) and (b), were the tests a six cases.

48

The board majority misdescribed the invention by confusing the embroidery with the substrate and in suppc inventor just applied a print to a rough substrate instead of a smooth one. It compared the invention with tl the basis of the elements employed being print and substrate. Actually, by both claim 1 and claim 10, there component elements. The embroidery is introduced between the print and the substrate. No print is applied substrate. It is all applied to the embroidery. The pattern, being "sculptured," intercepts the colors in the pr to the designer's intentions. The print and the pattern (embroidery) are made to "register" (claims 1 and 1C word), i.e., conform. They "mate."

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Certainly the board pointed to no prior art that separately suggested expressly or by implication a three-ele combination made up in this way. British in general teaches transfer prints on the substrate, as do Miles an remainder do not teach at all about transfer printing. When one skilled in the art at the time of the inventio considering all the prior art in combination, we wholly fail to perceive what more he would have found. The would have appeared to have been suggested was the use of transfer prints on rough substrates by which, variety of designs might have been achieved. Mating or registering are suggested nowhere in the prior art. does not show how to approach the results this inventor achieved. No prior art suggests expressly or by imp keeping the print off the substrate and providing a "sculptured" embroidery in a pattern to mate and registe print.

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Although British teaches transfer printing on lace, this patent does not envision the use of a pattern inserte transfer print and the lace substrate that would "mate" with the transfer print. Of course the lace substrate inherent pattern, but British makes no mention of it and does not even hint at mating the transfer print witl Without some express or implied suggestion, we cannot assume that one of ordinary skill in the art would h obvious to mate the transfer print with this pattern. More to the point, the inherent pattern in lace cannot b between the lace substrate and the transfer print because the pattern is part and parcel of the substrate. E\ lace can be "re-embroidered," as Butterick teaches, the embroidery on re-embroidered lace does not initiat but merely outlines the pattern of the lace itself; the single colored embroidery described in the first steps c claimed method, on the other hand, exhibits a pattern of its own designed to mate with the transfer print, a print off the substrate.

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The conclusion is the same under test (b) as it is under test (a). Under test (b), the person who considered combining the teachings of prior art references would not expect from the references or any implication to t therefrom that the great advance made by appellant's invention could be attained. The board never showed teachings of the prior art could be combined to make the invention.

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In re Sheckler, supra, may be taken as an example of a case where a combination of the teachings of prior suggested the inventor's result. The invention was for a building block for wall construction comprising a sa exterior portion were slabs of solid concrete and the interior, bonded to the slabs, was rigid light cellular he organic foam material. One prior art reference disclosed a reinforced concrete beam with an inner core of fc polymeric material. Another disclosed a building block consisting of two layers of load-bearing glass separat interior layer of heat-insulating foamed glass material.

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It could not have placed any great strain on the intellect of the court to sustain the board's conclusion of ob The court said, and we agree, it was not necessary that the prior art suggest expressly or in so many words "changes or possible improvements" the inventor made. It was only necessary that he apply "knowledge cle in the prior art." Sheckler, 438 F.2d at 1001, 168 U.S.P.Q. at 717. (Emphasis supplied.)

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If this last test is not met, the invention claimed would not have been obvious from the references.

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In re Imperato, supra, may be taken as an example of a case when combination of the teachings of prior ar did not suggest the inventor's result. The court therefore reversed the board's holding of obviousness. The i related to an improvement in the process of "beneficiating" low grade ore to prepare it for the blast furnace requires grinding the ore to a finely divided state in order to facilitate the removal of impurities. Then, howe be recombined into lumps for the furnace. The prior art used various carbonates for bonding to which the in free sulphur. Other prior art taught use of free sulphur only for bonding. The board thought it obvious to co two. The court, however, noted that combining both carbonates and sulphur achieved an unexpected result processes resulted in lump ore having high strength at low temperatures, but not at high temperatures, wh combination obtained a lump ore having high strength in both situations, an unexpected and unobvious resu of this case appears to be that prior art references in combination do not make an invention obvious unless the prior art references would suggest the advantage to be derived from combining their teachings. It does from the opinion that the inventor actually did anything not disclosed somewhere in the prior art references regard the case was less favorable for unobviousness than the case at bar, where none of the prior art refe disclosed an embroidery inserted between the print and the substrate, "registered" or mated the print with embroidery, not the substrate, and transferred the print to the insert, not to the substrate.

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For the foregoing reasons, it is clear that the principal rejection of claims 1, 4-6, and 9-11 cannot be sustair references relied upon by the board for this rejection (British, Miles, Vellins, and Butterick), either separatel combination, do not suggest that transfer printing techniques should be combined with embroidery techniq specific manner claimed in appellant's application. In view of all the art of record, we also hold that the sec rejection of claims 2, 3, and 8 must be reversed. While Cox, Haigh, and Sernaker disclose various aspects a

making of embroidered emblems, none of them disclose or suggest transfer printing; they do not envision u printing to create the effect of embroidery with different colored threads. Rather, they suggest using standa techniques, such as hand looming or embroidery with the Schiffli machine alone, to create the embroidered the absence of any suggestion to use teachings concerning transfer printing in the making of embroidered e conclude that appellant's claimed invention would not have been obvious to one of ordinary skill in the art fi seven references at the time of the invention.

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B. Whether the board correctly disregarded the secondary considerations.

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Finally, we hold that the "secondary considerations" that the Supreme Court stated might be of possible util obviousness determination, Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 693-694, 15 L.Ed. (1966), also require a finding of nonobviousness if the matter be otherwise doubtful. In an appeal of a rejec patent application, secondary considerations, such as commercial success, typically do not play a large part analysis of obviousness because the inventor usually waits until his patent issues before he swings producti gear. Thus, a detailed analysis of secondary considerations is more common in cases like John Deere, which infringement. If, however, a patent applicant properly presents evidence relating to these secondary consid board must always consider such evidence in connection with the determination of obviousness. In re Fielde Underwood, 471 F.2d 640, 644, 176 U.S.P.Q. 300, 303 (Cust. & Pat.App.1973).

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Appellant presented a considerable amount of such evidence. Despite the fact that a patent has not yet issu has been able to license his invention. Appellant's licensees have sold millions of the emblems, and the Gila attests that appellant's invention has met with great commercial success, has helped revitalize a depressed industry, and has introduced a new kind of emblem into the marketplace. The DeVries affidavit also attests uniqueness of appellant's invention. In addition, the record clearly shows that appellant's multicolored, emb emblems are considerably cheaper to produce than the prior art embroidered emblems. It is true the prior a relied on to establish obviousness had not been available to the inventor very long. Things apparently were in that industry. This might justify the thought that the want filled by the invention had not been felt very lo does not justify wholly ignoring these secondary considerations which here speak with unusual eloquence.

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In the face of all this evidence, the board was silent. Although the two affidavits in the record before us wer after the examiner's decision became final, they were submitted before the board reached its decision. Whil presented the DeVries affidavit to the examiner after his final action, 37 C.F.R. Sec. 1.116(b) (1982) would examiner to admit this evidence upon a showing of good cause. Under 37 C.F.R. Sec. 1.195 (1982), the boa power to admit the later Gilardone affidavit upon a similar showing. The record before us, however, is uncle the examiner did, in fact, admit the DeVries affidavit, and whether the board admitted the Gilardone affidav examiner nor the board mentioned these affidavits. In response to our specific question in oral argument, h solicitor admitted that the "commercial success" affidavits were before the board. In addition, the solicitor c brief the telling Gilardone affidavit and assured us that the board did consider evidence of commercial succe

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The argument (Br-15), that the Board of Appeals failed to consider the evidence of commercial success, is u Board specifically stated that they found the embroidered emblems "extremely attractive" (R-76). This appe recognition that the emblems would be well-received commercially. Appellant's affidavit (R-64) [the Gilardo shows only that the emblems have had good sales. There is no comparison with the sales of other embroide

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As we stated above, the Gilardone affidavit shows much more than "good sales." In addition, we reject the the board's bare compliment of the emblems as "extremely attractive" implies assignment of weight to appe commercial success evidence. To accept this notion would shrink the meaning of the phrase "secondary con beyond belief. The board in fact said nothing about the commercial success of appellant's invention, and no any of the other considerations the Supreme Court deemed relevant. Although the solicitor assures us that consider the evidence before us relating to secondary considerations, we do not agree with his analysis of tl nor do we find any support for this analysis in the board's opinion.

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The solicitor in effect has stipulated that the board considered the evidence, which necessarily implies that i filing of it on a showing of good cause, as to which there is no other evidence in the record. In view of this s appears it would be inappropriate to remand the case for the board to consider the same evidence a seconc only conclude that for some unexplained and, to us, unfathomable reason, the board found it insufficient to the, to it, plain indications of obviousness.

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For the reasons stated in this opinion, the decision of the board is reversed.

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REVERSED.

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OSCAR H. DAVIS, Circuit Judge, concurring in part and concurring in the result.

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I join in Parts I and II B of Judge Nichols' opinion. As for Part II A, my judicial microscope suggests to me th prior art is considered alone, the case is much closer than his opinion indicates. Differences there are, of co appellant's invention and the prior art, but it is not plain to me, from the bare references alone (especially t disclosing or suggesting transfer printing on lace and other rough-textured or somewhat "sculptured" mater invention was not obvious from the prior art. I need not, however, decide that unclear question on the refer For me the crucial insight is the "secondary consideration" of commercial success which (as Part II B of the spells out) appellant has fully proved, the Solicitor has not sought to rebut and has admitted was before the the Board failed properly to consider. Under Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 6 L.Ed.2d 545 (1966), that type of success is a relevant factor, and in this close case I think it decisive in sho nonobviousness.

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In Part II, 4 of the examiner's final rejection dated December 3, 1979, the examiner rejected appellant's cla 8-11. In the portion of this letter articulating the reasons for the rejection (Pt. II, 12), however, the examin

inadvertently omitted claim 11 from his discussion of the group of claims to which it belonged. The omissior typographical error. The board corrected this error when it discussed the examiner's rejection of claims 1, 4

U.S. Supreme Court

GRAHAM v. JOHN DEERE CO., 383 U.S. 1 (1966)

383 U.S. 1

GRAHAM ET AL. v. JOHN DEERE CO. OF KANSAS CITY ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT.
No. 11.
Argued October 14, 1965.
Decided February 21, 1966. *

[Footnote *] Together with No. 37, Calmar, Inc. v. Cook Chemical Co., and No. 43, Colgate-Palmolive Co. v. Cook Chemical Co., also on certiorari to the same court.

In No. 11 petitioners sued for infringement of a patent, consisting of a combination of old mechanical elements, for a device designed to absorb shock from plow shanks in rocky soil to prevent damage to the plow. In 1955 the Fifth Circuit held the patent valid, ruling that a combination is patentable when it produces an "old result in a cheaper and otherwise more advantageous way." Here the Eighth Circuit held that since there was no new result in the combination the patent was invalid. Petitioners in Nos. 37 and 43 filed actions for declaratory judgments declaring invalid respondent's patent relating to a plastic finger sprayer with a "hold-down" cap used as a built-in dispenser for containers with liquids, principally insecticides. By cross-action respondent claimed infringement. The District Court and the Court of Appeals sustained the patent. Held: The patents do not meet the test of the "nonobvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the pertinent art, set forth in 103 of the Patent Act of 1952, and are therefore invalid. Pp. 3-37. [383 U.S. 1, 2]

(a) In carrying out the constitutional command of Art. I, 8, that a patent system "promote the Progress of . . . useful Arts," Congress established the two statutory requirements of novelty and utility in the Patent Act of 1793. Pp. 3, 6, 12.

(b) This Court in Hotchkiss v. Greenwood, 11 How. 248 (1851), additionally conditioned the issuance of a patent upon the evidence of more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business. P. 11.

(c) In 103 of the 1952 Patent Act Congress added the statutory nonobvious subject matter requirement, originally expounded in Hotchkiss, which merely codified judicial precedents requiring a comparison of the subject matter sought to be patented and the prior art, tying patentable inventions to advances in the art. Although 103 places emphasis upon inquiries into obviousness, rather than into "invention," the general level of innovation necessary to sustain patentability remains unchanged under the 1952 Act. Pp. 14-17.

(d) This section permits a more practical test of patentability. The determination of "nonobviousness" is made after establishing the scope and content of prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. P. 17.

(e) With respect to each patent involved here the differences between the claims in issue and the pertinent prior art would have been obvious to a person reasonably skilled in that art. Pp. 25-26, 37.

333 F.2d 529, affirmed; 336 F.2d 110, reversed and remanded.

Orville O. Gold argued the cause for petitioners in No. 11. With him on the brief was Claude A. Fishburn. Dennis G. Lyons argued the cause for petitioners in Nos. 37 and 43. With him on the briefs for petitioner in No. 37 were Victor H. Kramer and Francis G. Cole. On the brief for petitioner in No. 43 were George H. Mortimer and Howard A. Crawford.

S. Tom Morris argued the cause for respondents in No. 11. With him on the brief were W. W. Gibson and Thomas E. Scofield. Gordon D. Schmidt argued the cause for respondent in Nos. 37 and 43. With him on [383 U.S. 1, 3] the brief were Carl E. Enggas, Hugh B. Cox and Charles A. Miller.

Briefs of amici curiae in No. 11 were filed by Roger Robb for the American Bar Association; by Stanton T. Lawrence, Jr., for the New York Patent Law Association; by George E. Frost for the Illinois State Bar Association; by J. Vincent Martin,

Alfred H. Evans and Russell E. Schlorff for the State Bar of Texas; and by Robert W. Hamilton for the School of Law of the University of Texas.

MR. JUSTICE CLARK delivered the opinion of the Court.

After a lapse of 15 years, the Court again focuses its attention on the patentability of inventions under the standard of Art. I, 8, cl. 8, of the Constitution and under the conditions prescribed by the laws of the United States. Since our last expression on patent validity, A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147 (1950), the Congress has for the first time expressly added a third statutory dimension to the two requirements of novelty and utility that had been the sole statutory test since the Patent Act of 1793. This is the test of obviousness, i. e., whether "the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." 103 of the Patent Act of 1952, 35 U.S.C. 103 (1964 ed.).

The questions, involved in each of the companion cases before us, are what effect the 1952 Act had upon traditional statutory and judicial tests of patentability and what definitive tests are now required. We have concluded that the 1952 Act was intended to codify judicial precedents embracing the principle long ago [383 U.S. 1, 4] announced by this Court in Hotchkiss v. Greenwood, 11 How. 248 (1851), and that, while the clear language of 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same.

I.

The Cases.

(a). No. 11, Graham v. John Deere Co., an infringement suit by petitioners, presents a conflict between two Circuits over the validity of a single patent on a "Clamp for vibrating Shank Plows." The invention, a combination of old mechanical elements, involves a device designed to absorb shock from plow shanks as they plow through rocky soil and thus to prevent damage to the plow. In 1955, the Fifth Circuit had held the patent valid under its rule that when a combination produces an "old result in a cheaper and otherwise more advantageous way," it is patentable. Jeoffroy Mfg., Inc. v. Graham, 219 F.2d 511, cert. denied, 350 U.S. 826. In 1964, the Eighth Circuit held, in the case at bar, that there was no new result in the patented combination and that the patent was, therefore, not valid. 333 F.2d 529, reversing 216 F. Supp. 272. We granted certiorari, 379 U.S. 956. Although we have determined that neither Circuit applied the correct test, we conclude that the patent is invalid under 103 and, therefore, we affirm the judgment of the Eighth Circuit.

(b). No. 37, Calmar, Inc. v. Cook Chemical Co., and No. 43, Colgate-Palmolive Co. v. Cook Chemical Co., both from the Eighth Circuit, were separate declaratory judgment actions, but were filed contemporaneously. Petitioner in Calmar is the manufacturer of a finger-operated sprayer with a "hold-down" cap of the type commonly seen on grocers' shelves inserted in bottles of insecticides and other liquids prior to shipment. Petitioner in Colgate-Palmolive is a purchaser of the sprayers [383 U.S. 1, 5] and uses them in the distribution of its products. Each action sought a declaration of invalidity and noninfringement of a patent on similar sprayers issued to Cook Chemical as assignee of Baxter I. Scoggin, Jr., the inventor. By cross-action, Cook Chemical claimed infringement. The actions were consolidated for trial and the patent was sustained by the District Court. 220 F. Supp. 414. The Court of Appeals affirmed, 336 F.2d 110, and we granted certiorari, 380 U.S. 949. We reverse.

Manifestly, the validity of each of these patents turns on the facts. The basic problems, however, are the same in each case and require initially a discussion of the constitutional and statutory provisions covering the patentability of the inventions.

II.

At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." Art. I, 8, cl. 8. 1 The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices - eventually curtailed by the Statute of Monopolies - of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. See Meinhardt, Inventions, Patents and Monopoly, pp. 30-35 (London, 1946). The Congress in the [383 U.S. 1, 6] exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of . . . useful Arts." This is the standard expressed in the Constitution and it may not

be ignored. And it is in this light that patent validity "requires reference to a standard written into the Constitution." A. & P. Tea Co. v. Supermarket Corp., supra, at 154 (concurring opinion).

Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. Gibbons v. Ogden, 9 Wheat. 1. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. McClurg v. Kingsland, 1 How. 202, 206. It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.

Congress quickly responded to the bidding of the Constitution by enacting the Patent Act of 1790 during the second session of the First Congress. It created an agency in the Department of State headed by the Secretary of State, the Secretary of the Department of War [383 U.S. 1, 7] and the Attorney General, any two of whom could issue a patent for a period not exceeding 14 years to any petitioner that "hath . . . invented or discovered any useful art, manufacture, . . . or device, or any improvement therein not before known or used" if the board found that "the invention or discovery [was] sufficiently useful and important . . . ." 1 Stat. 110. This group, whose members administered the patent system along with their other public duties, was known by its own designation as "Commissioners for the Promotion of Useful Arts."

Thomas Jefferson, who as Secretary of State was a member of the group, was its moving spirit and might well be called the "first administrator of our patent system." See Federico, Operation of the Patent Act of 1790, 18 J. Pat. Off. Soc. 237, 238 (1936). He was not only an administrator of the patent system under the 1790 Act, but was also the author of the 1793 Patent Act. In addition, Jefferson was himself an inventor of great note. His unpatented improvements on plows, to mention but one line of his inventions, won acclaim and recognition on both sides of the Atlantic. Because of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as his conclusions as to conditions for patentability under the statutory scheme, are worthy of note.

Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government. His abhorrence of monopoly extended initially to patents as well. From France, he wrote to Madison (July 1788) urging a Bill of Rights provision restricting monopoly, and as against the argument that [383 U.S. 1, 8] limited monopoly might serve to incite "ingenuity," he argued forcefully that "the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression," V Writings of Thomas Jefferson, at 47 (Ford ed., 1895).

His views ripened, however, and in another letter to Madison (Aug. 1789) after the drafting of the Bill of Rights, Jefferson stated that he would have been pleased by an express provision in this form:

> "Art. 9. Monopolies may be allowed to persons for their own productions in literature & their own inventions in the arts, for a term not exceeding - years but for no longer term & no other purpose." Id., at 113.

And he later wrote:

> "Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. . . . Nobody wishes more than I do that ingenuity should receive a liberal encouragement." Letter to Oliver Evans (May 1807), V Writings of Thomas Jefferson, at 75-76 (Washington ed.).

Jefferson's philosophy on the nature and purpose of the patent monopoly is expressed in a letter to Isaac McPherson (Aug. 1813), a portion of which we set out in the margin. 2 He rejected a natural-rights theory in [383 U.S. 1, 9] intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society - at odds with the inherent free nature of disclosed ideas - and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability.

As a member of the patent board for several years, Jefferson saw clearly the difficulty in "drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not." The board on which he served sought to draw such a line and formulated several rules which are preserved in [383 U.S. 1, 10] Jefferson's correspondence. 3 Despite the board's efforts, Jefferson saw "with what slow progress a system of general rules could be matured." Because of the "abundance" of cases and the fact that the investigations occupied "more time of the members of the board than they could spare from higher duties, the whole was turned over to the judiciary, to be matured into a system,

under which every one might know when his actions were safe and lawful." Letter to McPherson, supra, at 181, 182. Apparently Congress agreed with Jefferson and the board that the courts should develop additional conditions for patentability. Although the Patent Act was amended, revised or codified some 50 times between 1790 and 1950, Congress steered clear of a statutory set of requirements other than the bare novelty and utility tests reformulated in Jefferson's draft of the 1793 Patent Act.

III.

The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that "the things which are worth to the public the embarrassment [383 U.S. 1, 11] of an exclusive patent," as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.

This Court formulated a general condition of patentability in 1851 in Hotchkiss v. Greenwood, 11 How. 248. The patent involved a mere substitution of materials - porcelain or clay for wood or metal in doorknobs - and the Court condemned it, holding: 4

> "[U]nless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skilful mechanic, not that of the inventor." At p. 267.

Hotchkiss, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not. The Hotchkiss test laid the cornerstone of the judicial evolution suggested by Jefferson and left to the courts by Congress. The language in the case, and in those which followed, gave birth to "invention" as a word of legal art signifying patentable inventions. Yet, as this Court has observed, "[t]he truth is the word [`invention'] cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty [383 U.S. 1, 12] or not." McClain v. Ortmayer, 141 U.S. 419, 427 (1891); A. & P. Tea Co. v. Supermarket Corp., supra, at 151. Its use as a label brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar. The Hotchkiss formulation, however, lies not in any label, but in its functional approach to questions of patentability. In practice, Hotchkiss has required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined.

IV.

The 1952 Patent Act.

The Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in 101 and 102, and nonobviousness, the new statutory formulation, as set out in 103. The first two sections, which trace closely the 1874 codification, express the "new and useful" tests which have always existed in the statutory scheme and, for our purposes here, need no clarification. 5 The pivotal [383 U.S. 1, 13] section around which the present controversy centers is 103. It provides:

> " 103. Conditions for patentability; non-obvious subject matter
>
> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." [383 U.S. 1, 14]

The section is cast in relatively unambiguous terms. Patentability is to depend, in addition to novelty and utility, upon the "non-obvious" nature of the "subject matter sought to be patented" to a person having ordinary skill in the pertinent art.

The first sentence of this section is strongly reminiscent of the language in Hotchkiss. Both formulations place emphasis on the pertinent art existing at the time the invention was made and both are implicitly tied to advances in that art. The major distinction is that Congress has emphasized "nonobviousness" as the operative test of the section, rather than the less definite "invention" language of Hotchkiss that Congress thought had led to "a large variety" of expressions in decisions and

writings. In the title itself the Congress used the phrase "Conditions for patentability; non-obvious subject matter" (italics added), thus focusing upon "nonobviousness" rather than "invention." 6 The Senate and House Reports, S. Rep. No. 1979, 82d Cong., 2d Sess. (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), reflect this emphasis in these terms:

> "Section 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decisions of the courts. An invention which has been made, and which is new in the sense that the same thing has not been made before, may still not be patentable if the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent. That has been expressed in a large variety of ways in decisions of [383 U.S. 1, 15] the courts and in writings. Section 103 states this requirement in the title. It refers to the difference between the subject matter sought to be patented and the prior art, meaning what was known before as described in section 102. If this difference is such that the subject matter as a whole would have been obvious at the time to a person skilled in the art, then the subject matter cannot be patented.
>
> "That provision paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness. This section should have a stabilizing effect and minimize great departures which have appeared in some cases." H. R. Rep., supra, at 7; S. Rep., supra, at 6.

It is undisputed that this section was, for the first time, a statutory expression of an additional requirement for patentability, originally expressed in Hotchkiss. It also seems apparent that Congress intended by the last sentence of 103 to abolish the test it believed this Court announced in the controversial phrase "flash of creative genius," used in Cuno Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941). 7 [383 U.S. 1, 16]

It is contended, however, by some of the parties and by several of the amici that the first sentence of 103 was intended to sweep away judicial precedents and to lower the level of patentability. Others contend that the Congress intended to codify the essential purpose reflected in existing judicial precedents - the rejection of insignificant variations and innovations of a commonplace sort - and also to focus inquiries under 103 upon nonobviousness, rather than upon "invention," as a means of achieving more stability and predictability in determining patentability and validity.

The Reviser's Note to this section, 8 with apparent reference to Hotchkiss, recognizes that judicial requirements as to "lack of patentable novelty [have] been followed since at least as early as 1850." The note indicates that the section was inserted because it "may have some stabilizing effect, and also to serve as a basis for the addition at a later time of some criteria which may be worked out." To this same effect are the reports of both Houses, supra, which state that the first sentence [383 U.S. 1, 17] of the section "paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness."

We believe that this legislative history, as well as other sources, 9 shows that the revision was not intended by Congress to change the general level of patentable invention. We conclude that the section was intended merely as a codification of judicial precedents embracing the Hotchkiss condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability.

V.

Approached in this light, the 103 additional condition, when followed realistically, will permit a more practical test of patentability. The emphasis on nonobviousness is one of inquiry, not quality, and, as such, comports with the constitutional strictures.

While the ultimate question of patent validity is one of law, A. & P. Tea Co. v. Supermarket Corp., supra, at 155, the 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances [383 U.S. 1, 18] surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. See Note, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169 (1964).

This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act.

While we have focused attention on the appropriate standard to be applied by the courts, it must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office. To await litigation is - for all practical purposes - to debilitate the patent system. We have observed a notorious difference between the standards applied by the Patent Office and by the courts. While many reasons can be adduced to explain the discrepancy, one may well be the free rein often exercised by Examiners in their use of the concept of "invention." In this connection we note that the Patent Office is confronted with a most difficult task. Almost 100,000 applications for patents are filed each year. Of these, about 50,000 are granted and the backlog now runs well over 200,000. 1965 Annual Report of the Commissioner of Patents 13-14. This is itself a compelling reason for the Commissioner to strictly adhere to the 1952 Act as interpreted here. This would, we believe, not only expedite disposition but [383 U.S. 1, 19] bring about a closer concurrence between administrative and judicial precedent. 10

Although we conclude here that the inquiry which the Patent Office and the courts must make as to patentability must be beamed with greater intensity on the requirements of 103, it bears repeating that we find no change in the general strictness with which the overall test is to be applied. We have been urged to find in 103 a relaxed standard, supposedly a congressional reaction to the "increased standard" applied by this Court in its decisions over the last 20 or 30 years. The standard has remained invariable in this Court. Technology, however, has advanced - and with remarkable rapidity in the last 50 years. Moreover, the ambit of applicable art in given fields of science has widened by disciplines unheard of a half century ago. It is but an evenhanded application to require that those persons granted the benefit of a patent monopoly be charged with an awareness of these changed conditions. The same is true of the less technical, but still useful arts. He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office.

VI.

We now turn to the application of the conditions found necessary for patentability to the cases involved here:

A. The Patent in Issue in No. 11, Graham v. John Deere Co.

This patent, No. 2,627,798 (hereinafter called the '798 patent) relates to a spring clamp which permits plow shanks to be pushed upward when they hit obstructions [383 U.S. 1, 20] in the soil, and then springs the shanks back into normal position when the obstruction is passed over. The device, which we show diagrammatically in the accompanying sketches (Appendix, Fig. 1), is fixed to the plow frame as a unit. The mechanism around which the controversy centers is basically a hinge. The top half of it, known as the upper plate (marked 1 in the sketches), is a heavy metal piece clamped to the plow frame (2) and is stationary relative to the plow frame. The lower half of the hinge, known as the hinge plate (3), is connected to the rear of the upper plate by a hinge pin (4) and rotates downward with respect to it. The shank (5), which is bolted to the forward end of the hinge plate (at 6), runs beneath the plate and parallel to it for about nine inches, passes through a stirrup (7), and then continues backward for several feet curving down toward the ground. The chisel (8), which does the actual plowing, is attached to the rear end of the shank. As the plow frame is pulled forward, the chisel rips through the soil, thereby plowing it. In the normal position, the hinge plate and the shank are kept tight against the upper plate by a spring (9), which is atop the upper plate. A rod (10) runs through the center of the spring, extending down through holes in both plates and the shank. Its upper end is bolted to the top of the spring while its lower end is hooked against the underside of the shank.

When the chisel hits a rock or other obstruction in the soil, the obstruction forces the chisel and the rear portion of the shank to move upward. The shank is pivoted (at 11) against the rear of the hinge plate and pries open the hinge against the closing tendency of the spring. (See sketch labeled "Open Position," Appendix, Fig. 1.) This closing tendency is caused by the fact that, as the hinge is opened, the connecting rod is pulled downward and the spring is compressed. When the obstruction [383 U.S. 1, 21] is passed over, the upward force on the chisel disappears and the spring pulls the shank and hinge plate back into their original position. The lower, rear portion of the hinge plate is constructed in the form of a stirrup (7) which brackets the shank, passing around and beneath it. The shank fits loosely into the stirrup (permitting a slight up and down play). The stirrup is designed to prevent the shank from recoiling away from the hinge plate, and thus prevents excessive strain on the shank near its bolted connection. The stirrup also girds the shank, preventing it from fishtailing from side to side.

In practical use, a number of spring-hinge-shank combinations are clamped to a plow frame, forming a set of ground-working chisels capable of withstanding the shock of rocks and other obstructions in the soil without breaking the shanks.

Background of the Patent.

Chisel plows, as they are called, were developed for plowing in areas where the ground is relatively free from rocks or stones. Originally, the shanks were rigidly attached to the plow frames. When such plows were used in the rocky, glacial soils of some of the Northern States, they were found to have serious defects. As the chisels hit buried rocks, a vibratory motion was set up and tremendous forces were transmitted to the shank near its connection to the frame. The shanks would

break. Graham, one of the petitioners, sought to meet that problem, and in 1950 obtained a patent, U.S. No. 2,493,811 (hereinafter '811), on a spring clamp which solved some of the difficulties. Graham and his companies manufactured and sold the '811 clamps. In 1950, Graham modified the '811 structure and filed for a patent. That patent, the one in issue, was granted in 1953. This suit against competing plow manufacturers resulted from charges by petitioners that several of respondents' devices infringed the '798 patent. [383 U.S. 1, 22]

The Prior Art.

Five prior patents indicating the state of the art were cited by the Patent Office in the prosecution of the '798 application. Four of these patents, 10 other United States patents and two prior-use spring-clamp arrangements not of record in the '798 file wrapper were relied upon by respondents as revealing the prior art. The District Court and the Court of Appeals found that the prior art "as a whole in one form or another contains all of the mechanical elements of the 798 Patent." One of the prior-use clamp devices not before the Patent Examiner - Glencoe - was found to have "all of the elements."

We confine our discussion to the prior patent of Graham, '811, and to the Glencoe clamp device, both among the references asserted by respondents. The Graham '811 and '798 patent devices are similar in all elements, save two: (1) the stirrup and the bolted connection of the shank to the hinge plate do not appear in '811; and (2) the position of the shank is reversed, being placed in patent '811 above the hinge plate, sandwiched between it and the upper plate. The shank is held in place by the spring rod which is hooked against the bottom of the hinge plate passing through a slot in the shank. Other differences are of no consequence to our examination. In practice the '811 patent arrangement permitted the shank to wobble or fishtail because it was not rigidly fixed to the hinge plate; moreover, as the hinge plate was below the shank, the latter caused wear on the upper plate, a member difficult to repair or replace.

Graham's '798 patent application contained 12 claims. All were rejected as not distinguished from the Graham '811 patent. The inverted position of the shank was specifically rejected as was the bolting of the shank to the hinge plate. The Patent Office examiner found these to be "matters of design well within the expected skill of [383 U.S. 1, 23] the art and devoid of invention." Graham withdrew the original claims and substituted the two new ones which are substantially those in issue here. His contention was that wear was reduced in patent '798 between the shank and the heel or rear of the upper plate. 11 He also emphasized several new features, the relevant one here being that the bolt used to connect the hinge plate and shank maintained the upper face of the shank in continuing and constant contact with the underface of the hinge plate.

Graham did not urge before the Patent Office the greater "flexing" qualities of the '798 patent arrangement which he so heavily relied on in the courts. The sole element in patent '798 which petitioners argue before us is the interchanging of the shank and hinge plate and the consequences flowing from this arrangement. The contention is that this arrangement - which petitioners claim is not disclosed in the prior art - permits the shank to flex under stress for its entire length. As we have sketched (see sketch, "Graham '798 Patent" in Appendix, Fig. 2), when the chisel hits an obstruction the resultant force (A) pushes the rear of the shank upward and the shank pivots against the rear of the hinge plate at (C). The natural tendency is for that portion of the shank between the pivot point and the bolted connection (i. e., between C and D) to bow downward and away from the hinge plate. The maximum distance [383 U.S. 1, 24] (B) that the shank moves away from the plate is slight - for emphasis, greatly exaggerated in the sketches. This is so because of the strength of the shank and the short - nine inches or so - length of that portion of the shank between (C) and (D). On the contrary, in patent '811 (see sketch, "Graham '811 Patent" in Appendix, Fig. 2), the pivot point is the upper plate at point (c); and while the tendency for the shank to bow between points (c) and (d) is the same as in '798, the shank is restricted because of the underlying hinge plate and cannot flex as freely. In practical effect, the shank flexes only between points (a) and (c), and not along the entire length of the shank, as in '798. Petitioners say that this difference in flex, though small, effectively absorbs the tremendous forces of the shock of obstructions whereas prior art arrangements failed.

The Obviousness of the Differences.

We cannot agree with petitioners. We assume that the prior art does not disclose such an arrangement as petitioners claim in patent '798. Still we do not believe that the argument on which petitioners' contention is bottomed supports the validity of the patent. The tendency of the shank to flex is the same in all cases. If free-flexing, as petitioners now argue, is the crucial difference above the prior art, then it appears evident that the desired result would be obtainable by not boxing the shank within the confines of the hinge. 12 The only other effective place available in the arrangement was to attach it below the hinge plate and run it through a [383 U.S. 1, 25] stirrup or bracket that would not disturb its flexing qualities. Certainly a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length of the shank, would immediately see that the thing to do was what Graham did, i. e., invert the shank and the hinge plate.

Petitioners' argument basing validity on the free-flex theory raised for the first time on appeal is reminiscent of Lincoln Engineering Co. v. Stewart-Warner Corp., 303 U.S. 545 (1938), where the Court called such an effort "an afterthought. No such function . . . is hinted at in the specifications of the patent. If this were so vital an element in the functioning of the

apparatus it is strange that all mention of it was omitted." At p. 550. No "flexing" argument was raised in the Patent Office. Indeed, the trial judge specifically found that "flexing is not a claim of the patent in suit . . ." and would not permit interrogation as to flexing in the accused devices. Moreover, the clear testimony of petitioners' experts shows that the flexing advantages flowing from the '798 arrangement are not, in fact, a significant feature in the patent. 13

We find no nonobvious facets in the '798 arrangement. The wear and repair claims were sufficient to overcome [383 U.S. 1, 26] the patent examiner's original conclusions as to the validity of the patent. However, some of the prior art, notably Glencoe, was not before him. There the hinge plate is below the shank but, as the courts below found, all of the elements in the '798 patent are present in the Glencoe structure. Furthermore, even though the position of the shank and hinge plate appears reversed in Glencoe, the mechanical operation is identical. The shank there pivots about the underside of the stirrup, which in Glencoe is above the shank. In other words, the stirrup in Glencoe serves exactly the same function as the heel of the hinge plate in '798. The mere shifting of the wear point to the heel of the '798 hinge plate from the stirrup of Glencoe - itself a part of the hinge plate - presents no operative mechanical distinctions, much less nonobvious differences.

B. The Patent in Issue in No. 37, Calmar, Inc. v. Cook Chemical Co., and in No. 43, Colgate-Palmolive Co. v. Cook Chemical Co.

The single patent 14 involved in these cases relates to a plastic finger sprayer with a "hold-down" lid used as a built-in dispenser for containers or bottles packaging liquid products, principally household insecticides. Only the first two of the four claims in the patent are involved here and we, therefore, limit our discussion to them. We do not set out those claims here since they are printed in 220 F. Supp., at 417-418.

In essence the device here combines a finger-operated pump sprayer, mounted in a container or bottle by means of a container cap, with a plastic overcap which screws over the top of and depresses the sprayer (see Appendix, [383 U.S. 1, 27] Fig. 3). The pump sprayer passes through the container cap and extends down into the liquid in the container; the overcap fits over the pump sprayer and screws down on the outside of a collar mounting or retainer which is molded around the body of the sprayer. When the overcap is screwed down on this collar mounting a seal is formed by the engagement of a circular ridge or rib located above the threads on the collar mounting with a mating shoulder located inside the overcap above its threads. 15 The overcap, as it is screwed down, depresses the pump plunger rendering the pump inoperable and when the seal is effected, any liquid which might seep into the overcap through or around the pump is prevented from leaking out of the overcap. The overcap serves also to protect the sprayer head and prevent damage to it during shipment or merchandising. When the overcap is in place it does not reach the cap of the container or bottle and in no way engages it since a slight space is left between those two pieces.

The device, called a shipper-sprayer in the industry, is sold as an integrated unit with the overcap in place enabling the insecticide manufacturer to install it on the container or bottle of liquid in a single operation in an automated bottling process. The ultimate consumer simply unscrews and discards the overcap, the pump plunger springs up and the sprayer is ready for use.

The Background of the Patent.

For many years manufacturers engaged in the insecticide business had faced a serious problem in developing sprayers that could be integrated with the containers or bottles in which the insecticides were marketed. Originally, insecticides were applied through the use of tin [383 U.S. 1, 28] sprayers, not supplied by the manufacturer. In 1947, Cook Chemical, an insecticide manufacturer, began to furnish its customers with plastic pump dispensers purchased from Calmar. The dispenser was an unpatented finger-operated device mounted in a perforated cardboard holder and hung over the neck of the bottle or container. It was necessary for the ultimate consumer to remove the cap of the container and insert and attach the sprayer to the latter for use.

Hanging the sprayer on the side of the container or bottle was both expensive and troublesome. Packaging for shipment had to be a hand operation, and breakage and pilferage as well as the loss of the sprayer during shipment and retail display often occurred. Cook Chemical urged Calmar to develop an integrated sprayer that could be mounted directly in a container or bottle during the automated filling process and that would not leak during shipment or retail handling. Calmar did develop some such devices but for various reasons they were not completely successful. The situation was aggravated in 1954 by the entry of Colgate-Palmolive into the insecticide trade with its product marketed in aerosol spray cans. These containers, which used compressed gas as a propellent to dispense the liquid, did not require pump sprayers.

During the same year Calmar was acquired by the Drackett Company. Cook Chemical became apprehensive of its source of supply for pump sprayers and decided to manufacture its own through a subsidiary, Bakan Plastics, Inc. Initially, it copied its design from the unpatented Calmar sprayer, but an officer of Cook Chemical, Scoggin, was assigned to develop a more efficient device. By 1956 Scoggin had perfected the shipper-sprayer in suit and a patent was granted in 1959 to Cook

Chemical as his assignee. In the interim Cook Chemical began to use Scoggin's device and also marketed [383 U.S. 1, 29] it to the trade. The device was well received and soon became widely used.

In the meanwhile, Calmar employed two engineers, Corsette and Cooprider, to perfect a shipper-sprayer and by 1958 it began to market its SS-40, a device very much similar to Scoggin's. When the Scoggin patent issued, Cook Chemical charged Calmar's SS-40 with infringement and this suit followed.

The Opinions of the District Court and the Court of Appeals.

At the outset it is well to point up that the parties have always disagreed as to the scope and definition of the invention claimed in the patent in suit. Cook Chemical contends that the invention encompasses a unique combination of admittedly old elements and that patentability is found in the result produced. Its expert testified that the invention was "the first commercially successful, inexpensive integrated shipping closure pump unit which permitted automated assembly with a container of household insecticide or similar liquids to produce a practical, ready-to-use package which could be shipped without external leakage and which was so organized that the pump unit with its hold-down cap could be itself assembled and sealed and then later assembled and sealed on the container without breaking the first seal." Cook Chemical stresses the long-felt need in the industry for such a device; the inability of others to produce it; and its commercial success - all of which, contends Cook, evidences the nonobvious nature of the device at the time it was developed. On the other hand, Calmar says that the differences between Scoggin's shipper-sprayer and the prior art relate only to the design of the overcap and that the differences are so inconsequential that the device as a whole would have been obvious at the time of its invention to a person having ordinary skill in the art. [383 U.S. 1, 30]

Both courts accepted Cook Chemical's contentions. While the exact basis of the District Court's holding is uncertain, the court did find the subject matter of the patent new, useful and nonobvious. It concluded that Scoggin "had produced a sealed and protected sprayer unit which the manufacturer need only screw onto the top of its container in much the same fashion as a simple metal cap." 220 F. Supp., at 418. Its decision seems to be bottomed on the finding that the Scoggin sprayer solved the long-standing problem that had confronted the industry. 16 The Court of Appeals also found validity in the "novel 'marriage' of the sprayer with the insecticide container" which took years in discovery and in "the immediate commercial success" which it enjoyed. While finding that the individual elements of the invention were "not novel per se" the court found "nothing in the prior art suggesting Scoggin's unique combination of these old features . . . as would solve the . . . problems which for years beset the insecticide industry." It concluded that "the . . . [device] meets the exacting standard required for a combination of old elements to rise to the level of patentable invention by fulfilling the long-felt need with an economical, efficient, utilitarian apparatus which achieved novel results and immediate commercial success." 336 F.2d, at 114.

The Prior Art.

Only two of the five prior art patents cited by the Patent Office Examiner in the prosecution of Scoggin's application are necessary to our discussion, i. e., Lohse [383 U.S. 1, 31] U.S. Patent No. 2,119,884 (1938) and Mellon U.S. Patent No. 2,586,687 (1952). Others are cited by Calmar that were not before the Examiner, but of these our purposes require discussion of only the Livingstone U.S. Patent No. 2,715,480 (1953). Simplified drawings of each of these patents are reproduced in the Appendix, Figs. 4-6, for comparison and description.

The Lohse patent (Fig. 4) is a shipper-sprayer designed to perform the same function as Scoggin's device. The differences, recognized by the District Court, are found in the overcap seal which in Lohse is formed by the skirt of the overcap engaging a washer or gasket which rests upon the upper surface of the container cap. The court emphasized that in Lohse "[t]here are no seals above the threads and below the sprayer head." 220 F. Supp., at 419.

The Mellon patent (Fig. 5), however, discloses the idea of effecting a seal above the threads of the overcap. Mellon's device, likewise a shipper-sprayer, differs from Scoggin's in that its overcap screws directly on the container, and a gasket, rather than a rib, is used to effect the seal.

Finally, Livingstone (Fig. 6) shows a seal above the threads accomplished without the use of a gasket or washer. 17 Although Livingstone's arrangement was designed to cover and protect pouring spouts, his sealing feature is strikingly similar to Scoggin's. Livingstone uses a tongue and groove technique in which the tongue, located on the upper surface of the collar, fits into a groove on the inside of the overcap. Scoggin employed the rib and shoulder seal in the identical position and with less efficiency because the Livingstone technique [383 U.S. 1, 32] is inherently a more stable structure, forming an interlock that withstands distortion of the overcap when subjected to rough handling. Indeed, Cook Chemical has now incorporated the Livingstone closure into its own shipper-sprayers as had Calmar in its SS-40.

The Invalidity of the Patent.

Let us first return to the fundamental disagreement between the parties. Cook Chemical, as we noted at the outset, urges that the invention must be viewed as the overall combination, or - putting it in the language of the statute - that we must consider the subject matter sought to be patented taken as a whole. With this position, taken in the abstract, there is, of course, no quibble. But the history of the prosecution of the Scoggin application in the Patent Office reveals a substantial divergence in respondent's present position.

As originally submitted, the Scoggin application contained 15 claims which in very broad terms claimed the entire combination of spray pump and overcap. No mention of, or claim for, the sealing features was made. All 15 claims were rejected by the Examiner because (1) the applicant was vague and indefinite as to what the invention was, and (2) the claims were met by Lohse. Scoggin canceled these claims and submitted new ones. Upon a further series of rejections and new submissions, the Patent Office Examiner, after an office interview, at last relented. It is crystal clear that after the first rejection, Scoggin relied entirely upon the sealing arrangement as the exclusive patentable difference in his combination. It is likewise clear that it was on that feature that the Examiner allowed the claims. In fact, in a letter accompanying the final submission of claims, Scoggin, through his attorney, stated that "agreement was reached between the Honorable Examiner and applicant's attorney relative to limitations which must be in the claims in [383 U.S. 1, 33] order to define novelty over the previously applied disclosure of Lohse when considered in view of the newly cited patents of Mellon and Darley, Jr." (Italics added.)

Moreover, those limitations were specifically spelled out as (1) the use of a rib seal and (2) an overcap whose lower edge did not contact the container cap. Mellon was distinguished, as was the Darley patent, infra, n. 18, on the basis that although it disclosed a hold-down cap with a seal located above the threads, it did not disclose a rib seal disposed in such position as to cause the lower peripheral edge of the overcap "to be maintained out of contacting relationship with [the container] cap . . . when . . . [the overcap] was screwed [on] tightly . . . ." Scoggin maintained that the "obvious modification" of Lohse in view of Mellon would be merely to place the Lohse gasket above the threads with the lower edge of the overcap remaining in tight contact with the container cap or neck of the container itself. In other words, the Scoggin invention was limited to the use of a rib - rather than a washer or gasket - and the existence of a slight space between the overcap and the container cap.

It is, of course, well settled that an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office. Hogg v. Emerson, 11 How. 587 (1850); Crawford v. Heysinger, 123 U.S. 589 (1887). Claims as allowed must be read and interpreted with reference to rejected ones and to the state of the prior art; and claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent. Powers-Kennedy Co. v. Concrete Co., 282 U.S. 175, 185 -186 (1930); Schriber Co. v. Cleveland Trust Co., 311 U.S. 211, 220 -221 (1940). [383 U.S. 1, 34]

Here, the patentee obtained his patent only by accepting the limitations imposed by the Examiner. The claims were carefully drafted to reflect these limitations and Cook Chemical is not now free to assert a broader view of Scoggin's invention. The subject matter as a whole reduces, then, to the distinguishing features clearly incorporated into the claims. We now turn to those features.

As to the space between the skirt of the overcap and the container cap, the District Court found:

> "Certainly without a space so described, there could be no inner seal within the cap, but such a space is not new or novel, but it is necessary to the formation of the seal within the hold-down cap.
>
> "To me this language is descriptive of an element of the patent but not a part of the invention. It is too simple, really, to require much discussion. In this device the hold-down cap was intended to perform two functions - to hold down the sprayer head and to form a solid tight seal between the shoulder and the collar below. In assembling the element it is necessary to provide this space in order to form the seal." 220 F. Supp., at 420. (Italics added.)

The court correctly viewed the significance of that feature. We are at a loss to explain the Examiner's allowance on the basis of such a distinction. Scoggin was able to convince the Examiner that Mellon's cap contacted the bottle neck while his did not. Although the drawings included in the Mellon application show that the cap might touch the neck of the bottle when fully screwed down, there is nothing - absolutely nothing - which indicates that the cap was designed at any time to engage the bottle neck. It is palpably evident that Mellon embodies a seal formed by a gasket compressed [383 U.S. 1, 35] between the cap and the bottle neck. It follows that the cap in Mellon will not seal if it does not bear down on the gasket and this would be impractical, if not impossible, under the construction urged by Scoggin before the Examiner. Moreover, the space so strongly asserted by Cook Chemical appears quite plainly on the Livingstone device, a reference not cited by the Examiner.

The substitution of a rib built into a collar likewise presents no patentable difference above the prior art. It was fully disclosed and dedicated to the public in the Livingstone patent. Cook Chemical argues, however, that Livingstone is not in

the pertinent prior art because it relates to liquid containers having pouring spouts rather than pump sprayers. Apart from the fact that respondent made no such objection to similar references cited by the Examiner, 18 so restricted a view of the applicable prior art is not justified. The problems confronting Scoggin and the insecticide industry were not insecticide problems; they were mechanical closure problems. Closure devices in such a closely related art as pouring spouts for liquid containers are at the very least pertinent references. See, II Walker on Patents 260 (Deller ed. 1937).

Cook Chemical insists, however, that the development of a workable shipper-sprayer eluded Calmar, who had long and unsuccessfully sought to solve the problem. And, further, that the long-felt need in the industry for a device such as Scoggin's together with its wide commercial success supports its patentability. These legal inferences [383 U.S. 1, 36] or subtests do focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation. See Judge Learned Hand in Reiner v. I. Leon Co., 285 F.2d 501, 504 (1960). See also Note, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169 (1964). Such inquiries may lend a helping hand to the judiciary which, as Mr. Justice Frankfurter observed, is most ill-fitted to discharge the technological duties cast upon it by patent legislation. Marconi Wireless Co. v. United States, 320 U.S. 1, 60 (1943). They may also serve to "guard against slipping into use of hindsight," Monroe Auto Equipment Co. v. Heckethorn Mfg. & Sup. Co., 332 F.2d 406, 412 (1964), and to resist the temptation to read into the prior art the teachings of the invention in issue.

However, these factors do not, in the circumstances of this case, tip the scales of patentability. The Scoggin invention, as limited by the Patent Office and accepted by Scoggin, rests upon exceedingly small and quite nontechnical mechanical differences in a device which was old in the art. At the latest, those differences were rendered apparent in 1953 by the appearance of the Livingstone patent, and unsuccessful attempts to reach a solution to the problems confronting Scoggin made before that time became wholly irrelevant. It is also irrelevant that no one apparently chose to avail himself of knowledge stored in the Patent Office and readily available by the simple expedient of conducting a patent search - a prudent and nowadays common preliminary to well organized research. Mast, Foos & Co. v. Stover Mfg. Co., 177 U.S. 485 (1900). To us, the limited claims of the Scoggin patent are clearly evident from the prior art as it stood at the time of the invention. [383 U.S. 1, 37]

We conclude that the claims in issue in the Scoggin patent must fall as not meeting the test of 103, since the differences between them and the pertinent prior art would have been obvious to a person reasonably skilled in that art.

The judgment of the Court of Appeals in No. 11 is affirmed. The judgment of the Court of Appeals in Nos. 37 and 43 is reversed and the cases remanded to the District Court for disposition not inconsistent with this opinion.

It is so ordered.

MR. JUSTICE STEWART took no part in the consideration or decision of Nos. 37 and 43.

MR. JUSTICE FORTAS took no part in the consideration or decision of these cases. [383 U.S. 1, 38]

Footnotes

[Footnote 1] The provision appears in the Constitution spliced together with the copyright provision, which we omit as not relevant here. See H. R. Rep. No. 1923, 82d Cong., 2d Sess., at 4 (1952); DeWolf, An Outline of Copyright Law, p. 15 (Boston, 1925).

[Footnote 2] "Stable ownership is the gift of social law, and is given late in the progress of society. It would be curious then, if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses [383 U.S. 1, 9] the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from any body." VI Writings of Thomas Jefferson, at 180-181 (Washington ed.).

[Footnote 3] "[A] machine of which we are possessed, might be applied by every man to any use of which it is susceptible." Letter to Isaac McPherson, supra, at 181. "[A] change of material should not give title to a patent. As the making a ploughshare of cast rather than of wrought iron; a comb of iron instead of horn or of ivory . . . ." Ibid. "[A] mere change of form should give no right to a patent, as a high-quartered shoe instead of a low one; a round hat instead of a three-square; or a square bucket instead of a round one." Id., at 181-182. "[A combined use of old implements.] A man has a right to use a saw, an axe, a plane separately; may he not combine their uses on the same piece of wood?" Letter to Oliver Evans (Jan. 1814), VI Writings of Thomas Jefferson, at 298 (Washington ed.).

[Footnote 4] In historical retrospect, the specific result in Hotchkiss flows directly from an application of one of the rules of the original board of "Commissioners," n. 3, second rule, supra.

[Footnote 5] " 101. Inventions patentable "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." " 102. Conditions for patentability; novelty and loss of right to patent "A person shall be entitled to a patent unless - "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in [383 U.S. 1, 13] this country, more than one year prior to the date of the application for patent in the United States, or "(c) he has abandoned the invention, or "(d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application filed more than twelve months before the filing of the application in the United States, or "(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or "(f) he did not himself invent the subject matter sought to be patented, or "(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." The precursors of these sections are to be found in the Act of February 21, 1793, c. 11, 1 Stat. 318; Act of July 4, 1836, c. 357, 5 Stat. 117; Act of July 8, 1870, c. 230, 16 Stat. 198; Rev. Stat. 4886 (1874).

[Footnote 6] The corresponding provision in the preliminary draft was titled "Conditions for patentability, lack of invention" (italics added), Proposed Revision and Amendment of the Patent Laws, Preliminary Draft with Notes, House Committee on the Judiciary (Committee Print, 1950).

[Footnote 7] The sentence in which the phrase occurs reads: "[T]he new device, however useful it may be, must reveal the flash of creative genius, not merely the skill of the calling." At p. 91. Although some writers and lower courts found in the language connotations as to the frame of mind of the inventors, none were so intended. The opinion approved Hotchkiss specifically, and the reference to "flash of creative genius" was but a rhetorical embellishment of language going back to 1833. Cf. "exercise of genius," Shaw v. Cooper, 7 Pet. 292; "inventive genius," Reckendorfer v. Faber, 92 U.S. 347 (1876); Concrete Appliances Co. v. Gomery, 269 U.S. 177 ; "flash of thought," Densmore v. Scofield, 102 U.S. 375 (1880); "intuitive genius," Potts v. Creager, 155 U.S. 597 (1895). Rather than establishing a more exacting standard, Cuno merely rhetorically restated the requirement that the subject matter sought to be patented must be beyond the skill of the calling. It was the device, not [383 U.S. 1, 16] the invention, that had to reveal the "flash of creative genius." See Boyajian, The Flash of Creative Genius, An Alternative Interpretation, 25 J. Pat. Off. Soc. 776, 780, 781 (1943); Pacific Contact Laboratories, Inc. v. Solex Laboratories, Inc., 209 F.2d 529, 533; Brown & Sharpe Mfg. Co. v. Kar Engineering Co., 154 F.2d 48, 51-52; In re Shortell, 31 C. C. P. A. (Pat.) 1062, 1069, 142 F.2d 292, 295-296.

[Footnote 8] "There is no provision corresponding to the first sentence explicitly stated in the present statutes, but the refusal of patents by the Patent Office, and the holding of patents invalid by the courts, on the ground of lack of invention or lack of patentable novelty has been followed since at least as early as 1850. This paragraph is added with the view that an explicit statement in the statute may have some stabilizing effect, and also to serve as a basis for the addition at a later time of some criteria which may be worked out. "The second sentence states that patentability as to this requirement is not to be negatived by the manner in which the invention was made, that is, it is immaterial whether it resulted from long toil and experimentation or from a flash of genius."

[Footnote 9] See Efforts to Establish a Statutory Standard of Invention, Study No. 7, Senate Subcommittee on Patents, Trademarks, and Copyrights, 85th Cong., 1st Sess. (Committee Print, 1958); Hearings, Subcommittee No. 3, House Committee on the Judiciary, on H. R. 3760, 82d Cong., 1st Sess. (1951).

[Footnote 10] The President has appointed a Commission on the Patent System. Executive Order No. 11215, 30 Fed. Reg. 4661 (April 10, 1965). It is hoped that its studies may develop more efficient administrative procedures and techniques that will further expedite dispositions and at the same time insure the strict application of appropriate tests of patentability.

[Footnote 11] In '811, where the shank was above the hinge plate, an upward movement of the chisel forced the shank up against the underside of the rear of the upper plate. The upper plate thus provided the fulcrum about which the hinge was pried open. Because of this, as well as the location of the hinge pin, the shank rubbed against the heel of the upper plate causing wear both to the plate and to the shank. By relocating the hinge pin and by placing the hinge plate between the shank and the upper plate, as in '798, the rubbing was eliminated and the wear point was changed to the hinge plate, a member more easily removed or replaced for repair.

[Footnote 12] Even petitioners' expert testified to that effect: "Q. Given the same length of the forward portion of the clamp . . . you would anticipate that the magnitude of flex [in '798] would be precisely the same or substantially the same as in 811, wouldn't you? "A. I would think so."

[Footnote 13] "Q. . . . Do you regard the small degree of flex in the forward end of the shank that lies between the pivot point and the point of spring attachment to be of any significance or any importance to the functioning of a device such as 798? A. Unless you are approaching the elastic limit, I think this flexing will reduce the maximum stress at the point of pivot there, where the maximum stress does occur. I think it will reduce that. I don't know how much. "Q. Do you think it is a substantial factor, a factor of importance in the functioning of the structure? A. Not a great factor, no." The same expert previously testified similarly in Jeoffroy Mfg., Inc. v. Graham, 219 F.2d 511.

[Footnote 14] The patent is U.S. No. 2,870,943 issued in 1959 to Cook Chemical Co. as assignee of Baxter I. Scoggin, Jr., the inventor. In No. 37, Calmar is the manufacturer of an alleged infringing device, and, in No. 43, Colgate is a customer of Calmar and user of its device.

[Footnote 15] Our discussion here relates to the overcap seal. The container itself is sealed in the customary way through the use of a container gasket located between the container and the container cap.

[Footnote 16] "By the same reasoning, may it not also be said that if [the device] solved a long-sought need, it was likewise novel? If it meets the requirements of being new, novel and useful, it was the subject of invention, although it may have been a short step, nevertheless it was the last step that ended the journey. The last step is the one that wins and he who takes it when others could not, is entitled to patent protection." 220 F. Supp., at 421.

[Footnote 17] While the sealing feature was not specifically claimed in the Livingstone patent, it was disclosed in the drawings and specifications. Under long-settled law the feature became public property. Miller v. Brass Co., 104 U.S. 350, 352 (1882).

[Footnote 18] In addition to Livingstone and Mellon, the Examiner cited Slade, U.S. Patent No. 2,844,290 (hold-down cap for detergent cans having a pouring spout); Nilson, U.S. Patent No. 2,118,222 (combined cap and spout for liquid dispensing containers); Darley, Jr., U.S. Patent No. 1,447,712 (containers for toothpaste, cold creams and other semi-liquid substances).
[383 U.S. 1, 39]

HeRO™ Vascular Access Device: A Long Term Solution for Access-Challenged Patients.

Howard Katzman MD

Notes

INTRODUCTION

Tunneled dialysis catheters (TDCs) are considered the last resort "long-term" vascular access option compared to arteriovenous fistulas (AVFs) and grafts (AVGs). TDCs cause a high incidence of catheter-related bacteremia because the TDC penetrates the skin barrier creating a route for contamination; TDC-related bacteremias increase patient morbidity and mortality and result in significantly increased hospital costs.[1] TDCs deliver less effective dialysis due to reduced blood flow rates and are plagued with frequent malfunctions. [2-4] Additionally, traditional TDCs may induce central venous stenosis, which can limit future AVF or AVG options.[5] Despite these disadvantages and the success of the Fistula First Initiative, the number of patients dialyzing on TDCs continues to increase. As outlined in the DOPPS studies, the number of prevalent patients dialyzing on catheters virtually doubled from 15.2% in 1996-97 to 28.2% in 2002-2003[6] and as recently as 2006-2007, the End Stage Renal Disease Clinical Performance Measure Project (ESRD CPM project) noted a 2% increase in TDC catheter prevalence. Furthermore, over 70% of ESRD patients initiate dialysis with a catheter.[7]

Tunneled catheter dependency as a result of central venous stenosis, which inhibits peripheral access placement, can be significantly decreased by implantation of the HeRO™ Vascular Access Device. The FDA has cleared the HeRO™ device for maintaining vascular access in those patients who have exhausted all other peripheral access options. This device combines the functional status of an ePTFE graft and tunneled catheter into a permanently implanted subcutaneous access. The HeRO™ device consists of a 6 mm inner diameter (ID) ePTFE graft component fitted with a titanium connector that is surgically coupled at the time of implant to a subcutaneous 5 mm ID braided nitinol reinforced silicone outflow component designed to bypass peripheral stenosis and exit into the superior vena cava/right atrial junction via the internal jugular (IJ) vein, see **Figure 1** and **Figure 2**. The outflow component is introduced into the IJ vein using standard Seldinger technique and tunneled subcutaneously to the delta/pectoral groove in the shoulder area. The HeRO™ ePTFE graft is then tunneled from the shoulder area to the lower portion of the upper arm just above the elbow. The outflow component is then connected to the graft via the silicone encapsulated titanium connector and lastly, a graft to brachial artery anastomosis is created in the same manner as a conventional upper arm ePTFE graft. The HeRO™ device requires a heal-in period to allow the ePTFE to incorporate into the surrounding tissue before it can be accessed. During this time, a patient may require a bridging TDC for dialysis. Once the HeRO™ device is ready for cannulation (per K/DOQI graft cannulation guidelines), it is accessed in the same manner as a conventional graft eliminating the need for special training at dialysis centers.

Notes

Figure 1: The HeRO™ Device

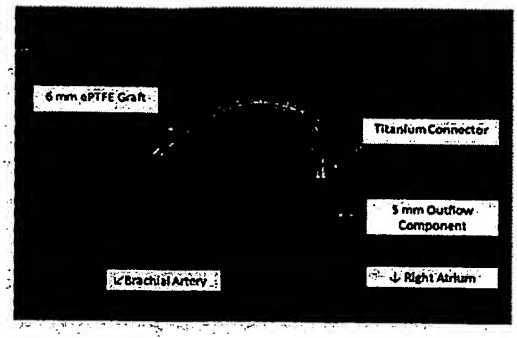
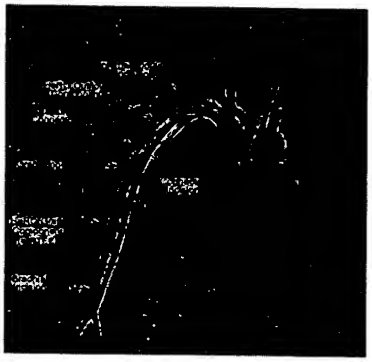


Figure 2: HeRO™ Device Implantation

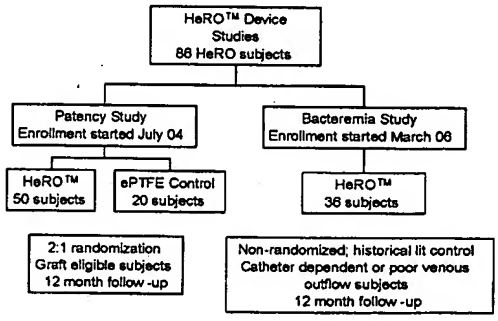


HeRO™ CLINICAL STUDY

Study Design

Enrollment commenced in July 2004 in a 2:1 randomized study of subjects eligible for an upper arm graft to evaluate HeRO™ patency compared to conventional ePTFE grafts (the Patency Study). A decreased number of graft placements resulting primarily from the success of the Fistula First Initiative limited patient recruitment in the study. However, since it was widely held that access-challenged patients would derive significant benefit from use of the HeRO™ device, a second study was initiated to evaluate the HeRO™ device in this patient population (the Bacteremia Study). Enrollment in the Bacteremia Study commenced in March 2006 based on the premise that access-challenged patients would experience a significant reduction in bacteremia rates with the HeRO™ device compared to a TDC. The multi-center FDA regulated studies are described in **Figure 3**. The primary endpoint in the HeRO™ Bacteremia Study was device/procedure-related bacteremia compared to a historic literature control in access-challenged subjects, and the primary endpoint in the HeRO™ Patency Study was secondary patency compared to an ePTFE control in graft-eligible subjects. In both studies, the data collected included bacteremia and patency rates, adverse events, and adequacy of dialysis.

Figure 3: HeRO™ Study Design



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Key inclusion criteria included subjects > 21 years of age, > 1 year life expectancy, hemodialysis dependent, a brachial artery >3 mm. Key exclusion criteria included known thrombophilia, active infection, ejection fraction < 20%, systolic blood pressure < 100 mmHg, ipsilateral implantable cardioverter defibrillator /pacemaker, and superior vena cava syndrome unless due to previous access.

CLINICAL STUDY RESULTS

Because the HeRO™ device was FDA cleared for use in access-challenged patients, the data presented focuses on this population (Bacteremia Study data). Thirty-six (36) subjects were treated in the Bacteremia Study at seven (7) sites. A total of 9,931 HeRO™ days (average 276 days per subject) accumulated in the Bacteremia Study with a mean 8.6 HeRO™ follow-up months. HeRO™ follow-up months include only HeRO™ follow-up days; follow-up days post HeRO™ device explant are excluded.

Demographics

As presented in **Table 1**, subjects enrolled in the HeRO™ Bacteremia Study had demographic characteristics consistent with the general ESRD population; however, this study included a statistically significant higher percentage of diabetic patients. Further, the access-challenged subjects in this study treated with the HeRO™ device were likely more progressed in their disease compared to the overall USRDS population as demonstrated in **Table 2** by their mean years on dialysis (5.1 years) and the large number of previous accesses.

Table 1: HeRO™ Bacteremia Study Demographic Data

	Bacteremia Study	USRDS Prevalent Population[I]
Number of Subjects[II]	38	341,319
Average number of previous bacteremias	1.8	Not reported
Mean age (years)	62.7	60.8
Caucasian	50.0%	55.3%
African-American	36.8%	37.2%
Hispanic	13.2%	14.8%
Diabetes Mellitus	68.4%	42.9%
Mean BMI	29.0	Not reported

[I]U.S. Renal Data System, USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2007 Table 2d Patient Demographics & Adjusted Rates, by Network: Point Prevalent Dialysis Patients, 2005

[II]Two subjects were enrolled and included in the demographic analysis that did not ultimately receive the HeRO™ device

Notes

Table 2: HeRO™ Bacteremia Study Access History

	Access History	Range
Mean years on dialysis ±SD	5.1 ±4.0	1-17
Previous fistula	66%	1-2
Previous graft	79%	1-5
Previous catheter	100%	1-16

Bacteremia Results

The Centers for Disease Control definition for a catheter-related bacteremia (i.e., device-related bacteremia) was used in the Bacteremia Study and is defined as a subject showing clinical signs of systemic infection including fever (> 100.4°F) or low temperature (< 95.9∞F) and one or more of the following: hypotension (systolic pressure < 90 mm Hg), low or elevated white blood cell count (< 4,000 or > 12,000) or a differential count showing 10% bands, tachycardia: pulse rate > 90 beats/minute and respiratory rate > 20/minute *and* two positive blood cultures for coagulase negative staphylococcus, diphtheroids, *Bacillus* spp., *Propionibacterium* spp., staphylococci, or micrococci *or* a single positive blood culture for other organisms and no other source for the infection is identified other than the device. Implant procedure-related bacteremias were defined as any bacteremia seeded by the subject's previous TDC (cultured at the time of HeRO™ device implant), any bacteremia that may have been seeded by a pre-existing infection elsewhere in the subject's body, possibly making the subject more susceptible to bacteremia in the peri-operative period, or where there is no other source for the bacteremia identified other than the HeRO™ device implant procedure. HeRO™ device and procedure-related bacteremias were combined for the Bacteremia Study primary endpoint analysis. The objective performance criteria (OPC) used in this study was a historical literature control for catheter-related bacteremia rates based upon an independent analysis of the IJ TDC-related literature rates, which included 15 articles on prospective or randomized studies that included at least 20 patients. This analysis resulted in a rate of 2.3/1,000 days.[9] This may be a conservative rate as the 2006 K/DOQI Guidelines report an IJ TDC-related bacteremia rate range of 1.6-5.5/1,000 days. All infections were adjudicated by an independent Clinical Events Committee (CEC) as to HeRO™ device and/or implant procedure relationship. All bacteremia events adjudicated as "definitely" or "probably" related to the HeRO™ device and/or implant procedure were considered "related" for this analysis.

The bacteremia data was analyzed in three cohorts as presented in **Table 3** below: 1) the bridging period, which included HeRO™ days from implant to bridging TDC removal, 2) the HeRO™ alone period after all bridging TDCs were removed and 3) the HeRO™ overall period, which included all days from time of HeRO™ implant through the

HeRO™ alone period. During the bridging period, 89% of subjects dialyzed via a TDC until HeRO™ graft heal-in. Of those requiring a bridging TDC, 41% utilized an IJ TDC and 59% utilized a femoral (FC) TDC. The large number of subjects requiring a FC TDC clearly demonstrated the limited access options remaining for the enrolled subjects due to peripheral and/or central venous stenosis. The mean TDC bridging time, as managed per site standard of care, was 38 days. There were seven (7) bacteremia events adjudicated by the CEC to be related to the HeRO™ device or implant procedure. This resulted in a HeRO™-related overall bacteremia rate of 0.70/1,000 days, which is statistically lower than the IJ TDC bacteremia historical literature control of 2.3/1,000 days. There were no HeRO™ device/procedure-related bacteremia events in the HeRO™ alone period once all bridging TDCs were removed (0.0/1,000 days).

Table 3: HeRO™ Device/Procedure-Related Bacteremia Results

Analyzed Cohorts	N	Related Bacteremia Events	HeRO™ Bacteremia Rate/1,000 days	UCB[I] (97.5%)	Catheter Literature Control/1,000 Days
HeRO™ Bridging IJ + FC (1373 days)	32[II]	7	5.10	10.50	1.6-6.9[8]
HeRO™ Alone (8525 days)	29	0	0.0	0.43	2.3[9]
HeRO™ OVERALL (9931 days)	***36***	***7***	***0.70***	***1.45***	***2.3***[9]

[I]Upper confidence bound
[II]Four subjects did not require a bridging TDC and dialyzed via a failing graft, fistula or peritoneal dialysis until HeRO™ heal-in

Of the seven (7) subjects that experienced a device/procedure-related bacteremia, four (4) required HeRO™ device explant (graft and outflow component), two (2) were explanted for reasons other than bacteremia (steal and right atrial clot) and the last subject was successfully treated via antibiotics, graft revision and connector replacement. This subject, a MRSA carrier, went on to dialyze via the HeRO™ device for 18 additional months.

Patency Data

The HeRO™ device patency data are presented in **Table 4** below compared to the catheter and graft patency literature. Although 8.4 HeRO™ mean follow-up months accumulated in the Bacteremia Study, HeRO™ patency data is presented at 6.8 mean follow-up months; the only analyzed dataset available with a mean follow-up period comparable to the 6 month patency data from the literature. Primary and secondary patency for the HeRO™ device at 6.8 mean HeRO™ months of follow-up was 44.4% and 100.0%, respectively. Because secondary patency was 100.0%, meaning no subjects loss use of their HeRO™ device due to patency issues, the functional patency classification was added to this analysis to present subjects who had loss use of their device for any reason including

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circumstances than loss of secondary patency, and is believed to more accurately represent actual HeRO™ device longevity. This functional patency definition may be comparable to some secondary patency definitions in the literature. The percent of HeRO™ subjects maintaining functional patency in the Bacteremia Study was 72.2% at 6.8 mean HeRO™ months.

Table 4: Percent of HeRO™ Subjects Maintaining Patency Versus Literature Controls

Patency	HeRO™ Bacteremia Study Patency at 6.8 HeRO™ Months	Catheter Literature Patency at 6 Months[10]	Graft Literature Patency at 6 Months[10]
Primary[I]	44.4% (16/36)	50%	58%
Primary-Assisted[II]	94.4% (34/36)	92%	68%
Secondary[III]	100.0% (36/36)	55%	76%
Functional[IV]	72.2% (26/36)	Not reported	Not reported

[I]**Loss of primary patency** was defined as the time point at which medical intervention is required to allow continued use of the device (device has completely thrombosed).
[II]**Primary-assisted patency** event defined as an intervention on a flowing device.
[III]**Loss of secondary patency** was defined as the time point at which the device could no longer be used for dialysis, the graft is abandoned, excised, or replaced due to patency. Any loss of secondary patency was automatically considered a loss of primary patency as well if the device had not already experienced a loss of primary patency.
[IV]**Loss of functional patency** was defined as the time point at which the device could no longer be used for dialysis due to loss of secondary patency, infection, steal, patient or physician preference, etc.

Intervention Data

In addition to patency, the rate of HeRO™ device interventions was also analyzed in the Bacteremia Study as presented in **Table 5**. All interventional procedures and use of thrombolytics were included in the intervention rate. The rate of intervention for the HeRO™ device was 2.5/year, which is comparable to the graft literature (1.6-2.4/year) and significantly better than the catheter literature (5.8/year).

Table 5: HeRO™ Device Intervention Data Versus Literature Controls

	HeRO™ Bacteremia Study	Catheter Literature[10]	Graft Literature[11]
Rate of Interventions	2.5/year[I]	5.8/year	1.6–2.4/year

[I]One clinically hypercoagulable subject excluded from this analysis

Adequacy of Dialysis

HeRO™ adequacy of dialysis data in **Table 6** below demonstrates that HeRO™ provides Kt/V values similar to AVGs and exceeds the adequacy of dialysis values provided by TDCs as well as the K/DOQI target guidelines. Of note, for each 0.1 unit decrease in Kt/V, it is estimated the mortality rate increases by 7%; therefore, the improvement in adequacy of dialysis values provided by the HeRO™ device in access-challenged patients could have a significant impact on mortality rates in this population.[12]

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Table 6: HeRO™ Adequacy of Dialysis

	HeRO™ Bacteremia Study Arm (N=36)	Catheter Literature[13]	ePTFE Graft Literature[13]	K/DOQI Adequacy of Hemodialysis Guidelines[14]
Kt/V	1.7	1.29-1.46 Literature Range	1.37-1.62 Literature Range	1.4 Target

Adverse Events

Adverse events in the study were analyzed and serious HeRO™ device and/or procedure-related adverse events were comparable to both the TDC and AVG literature. There were no unanticipated adverse events reported. Rates of steal associated with the HeRO™ device (2.6%) were comparable to the AVG literature (3.8%).[15]

DISCUSSION

Not surprisingly, the HeRO™ device has demonstrated a significant reduction in device/procedure-related bacteremia compared to TDCs since it is completely subcutaneous. The HeRO™-related bacteremia rate in this study, 0.70/1,000 days, includes those bacteremias adjudicated by the CEC as device and/or procedure-related and should not be misinterpreted as the overall bacteremia rate. Questions or criticisms about this data are most likely in regard to the bacteremia adjudication and how the CEC assigned responsibility to the device and/or implant procedure or determined the cause to be something other than the device, though, the CEC followed standard definitions of catheter-related bacteremia. Nevertheless, if the CEC's adjudication is discarded, in the HeRO™ alone period, the overall bacteremia rate regardless of relationship to the device and/or the implant procedure was 1.41/1,000 days. This rate is still lower than the TDC literature rate of 2.3/1,000 days. Furthermore, the historical literature control of 2.3/1,000 days has been criticized as being too low. At the time of this study, published data on prospective clinical trials were not available to establish a rate representing real-life clinical experience. More simply stated, access-challenged patients suffer from many comorbidities putting them at an even greater risk for infection compared to graft-eligible patients. Access-challenged patients with the HeRO™ device may still experience bacteremias associated with other comorbidities however this study has demonstrated that the HeRO™ device can offer significantly lower device/procedure-related bacteremia rates. This rate can be further reduced by decreasing the TDC bridging time.

The HeRO™ device provides continuous blood flow and is less prone to fibrin sheath occlusion (a typical TDC malfunction), therefore providing improved patency and optimum dialysis compared to a TDC. It was hypothesized that the HeRO™ device would provide patency and intervention rates superior to an AVG because the device is not subject to neointimal hyperplasia at the venous anastomosis, a typical AVG malfunction. However, these studies were not powered sufficiently to prove superior patency of the HeRO™ device versus a standard AVG though patency results were comparable. Graft-like patency is an improvement for catheter-dependent patients.

In conclusion, this study has shown that the HeRO™ device can provide a long term graft access for patients who are poor candidates for conventional AVGs or AVFs due to peripheral and/or central venous stenosis, offers a significant reduction in bacteremia compared to a TDC and offers the flow and patency of an ePTFE graft. There is a continuing clinical need for a long-term vascular access option for access-challenged patients. The HeRO™ device is a solution for these patients and ideally suited for the growing number of ESRD patients on hemodialysis who:

Have become catheter dependent or who are approaching catheter dependency

Are not candidates for an upper extremity AVF or AVG due to venous obstruction or are failing AVFs or AVGs due to venous obstruction

Are *de novo* with poor venous anatomy for peripheral long-term access or have a compromised central venous system or central venous stenosis

Are receiving inadequate dialysis via a TDC

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11:48 AM **Abstract No. 129**

Salvage of Failing Permanent Dialysis Access Using Peripheral Stent Grafts: A Community Hospital Experience.

H. Morrison[1], K. Schueler[1], B. Chou[1], A. Jobalia[2]; [1]Santa Clara Valley Medical Center - Department of Diagnostic Imaging, San Jose, CA; [2]Santa Clara Valley Medical Center - Department of Internal Medicine, Division of Nephrology, San Jose, CA.

PURPOSE: To determine the efficacy of using stent grafts for several types of hemodialysis graft and fistula failure including angioplasty failure, recurrent stenosis after angioplasty, recurrent thrombosis, vein rupture during angioplasty and symptomatic pseudoaneurysm.

MATERIALS & METHODS: The study is a retrospective analysis of outcomes after stent graft placement in patients with dialysis accesses at our institution between November 2004 and May 2008. IRB approval was obtained. All records and images were reviewed using hospital and nephrology service databases. 58 procedures were performed implanting 67 stent grafts within the dialysis circuits of 44 patients (15 male, 29 female, ages 25-85). All stent grafts placed in central veins (2) were excluded. Overlapping stent grafts implanted in a single procedure were regarded as regarded as a unit for statistical purposes. Accesses were 39 grafts (36/39 bovine carotid) and 5 native fistulae. Most graft configurations were forearm loop graft and the remainder were brachiobasilic, forearm straight and graft-fistula hybrid accesses. There were 2 radiocephalic and 3 upper arm fistulae. Indications for implantation were residual stenosis following angioplasty, early restenosis following angioplasty, recurrent thrombosis despite successful angioplasty, vein rupture during angioplasty and symptomatic pseudoaneurysm. Most were placed at the venous anastomosis of AV grafts. Stent grafts employed included Viabahn, Aspire, Fluency and Wallgraft. Technical success, clinical success and patency were assessed as per published SIR reporting standards (JVIR 14:S433-42 (2003)).

RESULTS: Technical success was 97%. Clinical success was 91%. Primary patency was 66%, 42%, 28% and 7% at 1, 3, 6 and 12 months, respectively. Primary assisted patency was 46%, 41% and 21% at 3, 6 and 12 months, respectively. Lesion patency was 55%, 44% and 24% at 3, 6, and 12 months, respectively. Access patency was 69%, 60% and 42% at 3, 6, and 12 months, respectively. 6 of 6 pseudoaneurysms were excluded without recurrence.

CONCLUSION: Stent graft implantation is effective for salvage of dialysis accesses.

12:00 PM **Abstract No. 130**

A New Long-Term Vascular Access Device for Catheter-Dependent Patients.

L. Dinwiddie; Vascular Access Education & Research, Cary, NC.

PURPOSE: This abstract reports the FDA study results for the HeRO™ Vascular Access Device, a long-term subcutaneous AV vascular access approved for hemodialysis patients who have exhausted all other peripheral options.

MATERIALS & METHODS: The HeRO™ device is a 6 mm ePTFE graft fitted with a titanium connector that is surgically connected to a subcutaneous 5 mm, braided nitinol-reinforced silicone outflow component, designed to direct blood flow to the IJ and transverse central venous stenoses to drain in the SVC/right atrial junction.

The HeRO™ device was studied in a multi-center study with the hypothesis that catheter-dependent patients would experience a significant reduction in bacteremia rates compared to an objective performance criterion (OPC) of literature TDC-related bacteremia rates.

RESULTS: HeRO™ clinical experience is based upon 86 implanted subjects, of which, 36 were catheter-dependent and the focus of this abstract. Subjects had 5.4 mean previous accesses (1-16 previous TDCs), 68% were diabetic and had 1.8 mean previous bacteremias. Mean follow-up was 8.4 months (9,931 HeRO™ days). The HeRO™ bacteremia rate was 0.70/1,000 days compared to the OPC of 2.3/1,000 days; a 70% decrease in the rate of bacteremia. All related bacteremias occurred during the bridging period while the TDC was still in place (59% dialyzed with a femoral TDC until HeRO™ incorporation). After HeRO™ cannulation and TDC removal, there were no related bacteremias. HeRO™ adequacy of dialysis, patency and intervention rates were all comparable to graft literature.

CONCLUSION: The HeRO™ device offers improved patency, adequacy of dialysis and bacteremia rates to catheter-dependent patients. HeRO™ eligible patients are catheter-dependent, failing an existing fistula or graft due to venous outflow obstruction, or are new to dialysis with poor venous anatomy for peripheral access and a minimum 3 mm artery to provide sufficient inflow to maintain dialysis adequacy. The HeRO™ device may require declotting like conventional grafts, and uses standard non-rotational, aspiration techniques. The interventional team will have primary responsibility in maintaining patency.

Scientific Session 14
Genes, Radiation Protection and Pediatric Intervention

Tuesday, March 10, 2009
10:00 AM - 12:12 PM
Room: 16B

10:00 AM **Abstract No. 131**

Autologous Vaccination Against Hepatic Cancers with Radiotherapy, Intratumoral Poly-ICLC and Hepatic Artery Embolization (HAE).

A. De la Torre[1], C. Cathcart[3], W. Bhatti[2], P. Kisza[2], S. Contractor[2]; [1]UMDNJ - Surgery, Newark, NJ; [2]UMDNJ - Radiology, Newark, NJ; [3]UMDNJ - Radiation Oncology, Newark, NJ.

PURPOSE: Immune mechanisms have not been exploited in treating HCC. We report an ongoing phase I trial using: 1) low dose 3D conformal radiation (3DRT) to increase HCC tumor antigen release, 2) US guided tumor injection of the dsRNA Toll Like Receptor 3 (TLR3) ligand poly-ICLC, (Hiltonol®) to initiate adaptive immune responses in the local environment, 3) bland HAE of the targeted lesion, 4) systemic IM poly-ICLC to boost overall immunity.

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in Re Leonard R. Kahn., 441 F.3d 977 (Fed. Cir. 2006)

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US Code - Title 35: Patents - 35 USC 112 - Sec. 112. Specification

US Code - Title 35: Patents - 35 USC 103 - Sec. 103. Conditions for patentability; non-obvious subject matter

U.S. Supreme Court - Dann v. Johnston, 425 U.S. 219 (1976)

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U.S. Court of Appeals for the Fed. Cir. - Aventis Pharma Deutschland GMBH, et al. v. Lupin, LTD., et al. (Fed. Cir. 2007)

U.S. Court of Appeals for the Fed. Cir. - Optivus Technology, Inc., Plaintiff-Appellant, and Loma Linda University Medical Center, Plaintiff-Appellant, v. Ion Beam Applications S.A., Defendant-Cross Appellant., 469 F.3d 978 (Fed. Cir. 2006)

U.S. Court of Appeals for the Fed. Cir. - Eli Lilly and Company and Lilly Industries Limited, Plaintiffs-Appellees, v. Zenith Goldline Pharmaceuticals, Inc. (Now Known as Ivax Pharmaceuticals, Inc.),

Defendant-Appellant, and Teva Pharmaceuticals Usa, Inc., Defendant-Appellant, and Dr. Reddy'S Laboratories, Ltd., Defendant-Appellant., 471 F.3d 1369 (Fed. Cir. 2006)

U.S. Court of Appeals for the Fed. Cir. - Abbott Laboratories, Plaintiff-Appellee, v. Andrx Pharmaceuticals, Inc., and Roxane Laboratories, Inc., Defendants, and Teva Pharmaceuticals Usa, Inc., Defendant-Appellant., 452 F.3d 1331 (Fed. Cir. 2006)

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U.S. Court of Appeals for the Fed. Cir. - Ormco Corporation, Plaintiff/Counterdefendant-Appellant, and Allesee Orthodontic Appliances, Inc., Counterdefendant-Appellant, v. Align Technology, Inc., Defendant/Counterclaimant-Appellee., 463 F.3d 1299 (Fed. Cir. 2006) Plaintiff/Counterdefendant-Appellant, and Allesee Orthodontic Appliances, Inc., Counterdefendant-Appellant, **v. Align Technology, Inc., Defendant/Counterclaimant-Appellee.**

- *See all citations to this document*

Text:

John M. Whealan, Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, for the Director of the United States Patent and Trademark Office. With him on the brief were Linda Moncys Isacson and Raymond T. Chen, Associate Solicitors. Of counsel was Mary L. Kelly.

Before MICHEL, Chief Judge, LINN, and PROST, Circuit Judges.

LINN, Circuit Judge.

Leonard R. Kahn ("Kahn") appeals from the final decision of the Board of Patent Appeals and Interferences ("Board") concluding that claims 1-20 in patent application number 08/773,282 ("the '282 application") are unpatentable as obvious under 35 U.S.C. 103.1 Because the factual findings underlying the Board's conclusion are supported by substantial evidence, and because the Board did not commit legal error in concluding that the claims would have been obvious, we affirm.

I. BACKGROUND

A. The Invention

The '282 application, filed on December 24, 1996 as a continuation-in-part of a series of continuing applications dating back to 1989, involves a "reading machine" that may be used by the blind. Prior to the application, machines that employed memory and display components by which material could be "read" using hand-held optical pens and speech synthesizers were known in the art. While a user can control these devices by hand to repeat words and to read at various speeds, such control is cumbersome, which makes it difficult for a blind user to study complex publications. Kahn addressed this problem and claims invention in a device that is operated by eye control and sound localization such that it can read out loud the word "looked at" by the user.

Kahn treats claims 1-20 as a group with claim 1 being representative:

1. A reading machine suitable for use by totally blind individuals for reading the complete text, or a selected portion thereof, of a document stored in storage means, at the option of the user, comprising:

(a) means of storing at least a portion of the text of the document to be read,

(b) means for retrieving a selected portion of said stored text made available for immediate "reading,"

(c) means for producing an acoustical display of the selected portion of said stored text, in a page-like format,

(d) means for determining the location on the acoustical display towards which the user is "looking," and

(e) means for generating speech sounds verbalizing the word that is formatted to appear on the acoustical display at the location the user is "looking" towards.

A preferred embodiment of the '282 patent is illustrated below in Figure 1. NOTE: OPINION CONTAINING TABLE OR OTHER DATA THAT IS NOT VIEWABLE

In operation,

[t]he information being "read" ... is fed through intermediate storage means to speech synthesizer means for converting the written information to electrical waves representing speech sounds. These electric waves are fed to ... a four speaker array wherein the speakers are located in a fashion so that the artificial sound image can be placed at various points on the artificial screen or page allowing the user to hear the words at the desired locations. These locations would be selected by the user looking at a specific location on the artificial screen or page.

The user would then move his or her eyes to "look" where the next word would be expected to appear, i.e., directly to the right of the spoken word. This would then cause the next word to be "spoken" and the sound image would appear slightly to the right. This motion is achieved by energizing the four speaker array with different levels of audio power....

When the user completes the "reading" of the last word on the page, ... the reader would have the option of rereading a section on the page or causing the page to be "turned." If the user wishes to reread ..., he can direct his attention to the material to be reread by "looking" at the portion of the page where he remembers hearing the material.

On the other hand, if he wishes to continue reading the material he can turn the page by looking along the bottom line past the right hand edge of the "page". The first word on the new page would be heard when the reader directed his or her attention to the upper left hand corner of the page where the first word on the new page would be expected.

'282 application at 11-13.

According to the specification, the device can employ a conventional scanner to input data; a conventional character recognition device to translate and send data to a storage device; and a page generator to take data from the storage device and format it for a visual display and for a word selector, the latter of which can send the data to a conventional speech synthesizer. After an optical sensor detects where a user is "looking" and a word is "selected" for vocalization, the synthesizer feeds an audio signal

to a localizer control. Loud speakers are arranged at the corners of the "page" to allow the user to confirm localization of sound. The specification further indicates that

[t]here are a number of devices available for sensing where an individual is looking. For example, Garwin et. al. 4,595,990 ..., Anderson et. al. 4,579,533... and Stanton 4,322,744 .... More specifically, Anderson's [sic] patent discusses feed-back which may be visual, auditory or tactile to verify decisions by eye control equipment.

However, such inventions are not suitable for totally blind individuals who are not verifying where they are looking but are using their eyes to direct which part of the artificial page should be read to produce a sound image. This makes essential a two dimensional stereo sound stage which the blind person solely depends upon.

'282 application at 16.

B. The Prior Art

The Board's rejection was based on Garwin et al., U.S. Patent No. 4,595,990 (issued June 17, 1986) ("Garwin"), in view of Anderson et al., U.S. Patent No. 4,406,626 (issued Sept. 27, 1983) ("Anderson '626"), Anderson et al., U.S. Patent No. 4,579,533 (issued April 1, 1986) ("Anderson '533"), and Stanton, U.S. Patent No. 4,322,744 (issued March 30, 1982) ("Stanton"). The Board alternatively used Anderson '626 or '533 as primary references.

Garwin discloses an eye-controlled interactive information processor that senses the portion of a visual display at which the user is looking. The processor is connected to the display, which, in turn, can be partitioned so that different information is displayed in discrete areas. By gazing in different directions, the user informs the processor of the displayed item that is selected. Garwin, col. 2, ll. 60-68. The preferred embodiment employs a reflected light eye-tracking device to determine where the user is looking. Id., col. 3, l. 66-col. 4, l. 62. The eye-interactive control generally uses a technique where the user is presented with a number of targets having some meaning, such as "words or phrases" displayed on screen. Id., col. 9, ll. 62-67. "Visual, auditory or tactile" feedback is then given to the user to indicate that a selection has been received. Id., col. 2, ll. 10-11; col. 11, ll. 59-64. The user then can verify or cancel the selection. Id., col. 10, ll. 1-6. Garwin states that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus." Id., col. 2, ll. 50-53. It can be used for "request[ing] display of a page of text from a ... table of contents," id., col. 3, ll. 42-44, or "[other] presentation of textual material," id., col. 10, ll. 31-33.

Anderson '626 discloses an interactive "electronic teaching aid" which enables a user viewing text on a display to designate any words or portion of text for immediate audible vocalization. Anderson '626, col. 1, l. 8; col. 2, ll. 11-17. The components include: a selector switch, which when in the "text" position, causes data to be transmitted to a monitor and displayed in legible form, id., col. 3, ll. 27-31; an advance button, which when depressed allows the user to select and retrieve the next page of text from memory, id., col. 3, ll. 31-41; a memory, which can store each word of the text coded for speech, id., col. 3, l. 66-col. 4, l. 6; and a word designator light pen, which the user can place on a word to hear the word vocalized through the speaker, id., col. 3, ll. 54-68; col. 10, ll. 51-58. Anderson '533 discloses an improved microprocessor-based version of Anderson '626. Anderson '533, col. 1, ll. 19-24, 41-56.

Stanton discloses an acoustical imaging system for use by visually impaired individuals that uses horizontal and vertical directional sound to represent visual aspects of an environment. Stanton states that a user can locate "the position of a virtual sound source as representing a point in space" such that

different signals may represent different directions. Stanton, col. 1, ll. 58-61. The preferred embodiment features four loud speakers or transducers mounted at the corners of a vertical display panel. Id., col. 2, ll. 54-55. When the user moves the cursor, the sound emanating from the speakers is phase shifted to produce a virtual sound seeming to come from a particular location related to the position of the cursor. Id., col. 1, l. 66-col. 2, l. 2; col. 2, ll. 55-63. In another embodiment, a quadraphonic headset is used in place of the transducers to achieve the effect of producing a virtual sound identifying a position. Id., col. 4, ll. 26-35. Stanton states that the device may be used as a "rudimentary reading device." Id., col. 1, ll. 62.

C. The Board Decisions

Kahn filed the '282 application with 22 claims as a continuation-in-part of application number 07/645,102 ("the '102 application"), which was filed in 1991. The '102 application was a continuation-in-part of a series of abandoned continuing applications dating back to application number 07/338,597, which was filed in 1989. While claims 21 and 22 of the '282 application are not at issue in this appeal, the Board addressed those claims on several occasions, which led to the creation of a substantial Board history. As a result, the final decision with respect to the obviousness rejection of claims 1-20 spans three decisions, which include Ex Parte Kahn, No.2004-1091 (B.P.A.I. June 30, 2004) ("2004 decision"); and Ex Parte Kahn, No.2000-1130 (B.P.A.I. Feb. 24, 2003) ("2003 decision"); and Ex Parte Kahn, No. 94-2233 (B.P.A.I. Sept. 21, 1995) ("1995 decision").

In its 1995 decision, after reversing the examiner's anticipation rejection, the Board sua sponte rejected the relevant claims under § 103. The Board found that Garwin taught "the concepts of determining where on a display screen a user is `looking' ... and giving either visual or auditory feedback to the user" and that "[w]hile nothing specific is said as to acoustically reproducing a word displayed at that location, common sense ... indicate[s] that such an auditory feedback response is appropriate in view of such auditory feedback confirmation clearly suggested by Anderson '533 or '626." 1995 decision, slip op. at 5 (emphasis in original). The Board found that "to whatever extent Garwin is not concerned with text per se, [the Anderson] references are" and "teach the advantages of text display with audio reproduction," concluding that

the artisan would have found it to have been obvious to have modified Garwin for display of text passages and selection of works therefrom with vocalization thereof as feedback confirmation, all as taught by Anderson '626 or '533 ... [or] to have modified either of these Anderson references to use the eye control of Garwin so that the user's hands would have been free for other tasks.

Id., slip op. at 5-6. The Board found that Stanton "teaches the benefit of acoustic imaging in reading systems" and that "[i]t would have, thus, been further obvious to the artisan to add advantageous acoustic imaging to either of the above-noted modified devices of Garwin or the Anderson patents which would have word positions acoustically and visually indicated." Id., slip op. at 6.

In its 2003 decision, the Board expressly incorporated the findings and rationale from both its 1995 decision and the Examiner's Answer filed on April 24, 2000. 2003 decision, slip op. at 3-4. In the Answer, the Examiner had explained that Garwin teaches "a buffer memory which stores at least a portion of the information derived from sensing means and means for subsequently retrieving the sensed information," "means for displaying stored written text," and "means for determining which word of the displayed text the user is looking towards"; that Anderson '626 teaches "means for generating speech sounds verbalizing the looked at word"; and that Stanton teaches "means for verbalizing each word the user's eyes are directed towards in two dimensional stereo." Examiner's Answer at 5-6. Rejecting Kahn's argument that hindsight drove the combination of references, the Board reiterated that the rationale of the 1995 decision was correct and explained that motivation "clearly is based upon a prospective look at

the state of the art." 2003 decision, slip op. at 8-11.

The Board addressed several other arguments. First, the Board rejected the argument that the invention's intended use supports patentability, noting that "the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus [from] a prior art apparatus satisfying the claimed structural limitations." Id. at 5-6. Second, the Board rejected the argument that because "the purposes of the [prior art] references... are different from the [invention's] purpose," the invention is non-obvious, explaining that "[t]he law ... does not require that references be combined for reasons contemplated by an inventor" and that "prior art need not suggest the same problem set forth by appellant." Id. at 6-7. Third, the Board rejected the arguments that features of a secondary reference be capable of incorporation into the structure of a primary reference and that the invention be suggested completely by one reference. Id. at 7. Finally, the Board rejected a "long-felt need" argument, explaining that Khan had not presented any objective evidence of a long-standing problem or long-standing need in the art. Id. at 11-12.

In its 2004 decision, the Board entered a final rejection of claims 1-20 based on its 2003 decision. Kahn timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. 1295(a)(4)(A).

II. DISCUSSION

A. The Parties' Arguments

Khan advances two main arguments. First, Khan asserts that the Board's finding of motivation to combine was unsupported by substantial evidence. Citing In re Lee, 277 F.3d 1338 (Fed.Cir.2002), and In re Rouffet, 149 F.3d 1350 (Fed.Cir. 1998), Khan argues that the Board overstated the knowledge of the skilled artisan and employed improper hindsight. Specifically, Khan asserts that a skilled artisan would not have sought to augment Garwin with sound because the resulting device would be more expensive and less reliable for the purpose intended by Garwin. He contends that just because Stanton teaches use of sound to confirm a visual perception of a shape like a letter ? which provides a "rudimentary" reading capability ? does not mean that the reference teaches how to enable a blind user to "read" and "reread" entire words and phrases quickly. Khan further contends that Stanton teaches away from a system that employs iris eye direction sensing because Stanton requires the user to hold his head steady, because eyes are not involved in its localization procedure, and because the combined device would be expensive and inoperable. Second, Khan argues that the court should take "judicial notice" that his reading machine addresses a "long-felt, but unresolved need," and that this consideration is sufficient to rebut a prima facie case of obviousness.

The Patent and Trademark Office ("PTO") counters that Lee and Rouffet are distinguishable because here the Board identified motivations to combine the references based on specific statements in the references and on the nature of the problem to be solved. As to long-felt need, the PTO argues that Kahn proffered no actual evidence, and that Kahn's argument alone is insufficient to rebut a prima facie case.

B. Standard of Review

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. 103(a) (2000); Graham v. John Deere Co., 383 U.S. 1, 13-14, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying findings of fact. In re Dembiczak, 175 F.3d 994, 998 (Fed. Cir.1999). We review the Board's ultimate determination of obviousness de

novo. Id. However, we review the Board's underlying factual findings, including a finding of a motivation to combine, for substantial evidence. In re Gartside, 203 F.3d 1305, 1316 (Fed.Cir.2000).

Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence. Id. at 1312 (citing Consol. Edison Co. v. NLRB, 305 U.S. 197, 229-30, 59 S.Ct. 206, 83 L.Ed. 126 (1938)). It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. Consol. Edison, 305 U.S. at 229-30, 59 S.Ct. 206. In reviewing the record, we must take into account evidence that both justifies and detracts from the factual determinations. Gartside, 203 F.3d at 1312 (citing Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88, 71 S.Ct. 456, 95 L.Ed. 456 (1951)). We note that the possibility of drawing two inconsistent conclusions from the evidence does not prevent the Board's findings from being supported by substantial evidence. Id. Indeed, if a reasonable mind might accept the evidence as adequate to support the factual conclusions drawn by the Board, then we must uphold the Board's determination. Id. C. Analysis

In assessing whether subject matter would have been non-obvious under § 103, the Board follows the guidance of the Supreme Court in Graham v. John Deere Co. The Board determines "`the scope and content of the prior art,'" ascertains "`the differences between the prior art and the claims at issue,'" and resolves "`the level of ordinary skill in the pertinent art.'" Dann v. Johnston, 425 U.S. 219, 226, 96 S.Ct. 1393, 47 L.Ed.2d 692 (1976) (quoting Graham, 383 U.S. at 17, 86 S.Ct. 684). Against this background, the Board determines whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. Graham, 383 U.S. at 17, 86 S.Ct. 684. In making this determination, the Board can assess evidence related to secondary indicia of nonobviousness like "commercial success, long felt but unresolved needs, failure of others, etc." Id., 383 at 17-18, 86 S.Ct. 684; accord Rouffet, 149 F.3d at 1355. We have explained that

[t]o reject claims in an application under section 103, an examiner must show an unrebutted prima facie case of obviousness.... On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of prima facie obviousness or by rebutting the prima facie case with evidence of secondary indicia of nonobviousness.

Rouffet, 149 F.3d at 1355.

Most inventions arise from a combination of old elements and each element may often be found in the prior art. Id. at 1357. However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Id. at 1355, 1357. Rather, to establish a prima facie case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. Id. In practice, this requires that the Board "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." Id. at 1357-59. This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the Graham test.

When the Board does not explain the motivation, or the suggestion or teaching, that would have led the skilled artisan at the time of the invention to the claimed combination as a whole, we infer that the Board used hindsight to conclude that the invention was obvious. Id. at 1358. The "motivation-suggestion-teaching" requirement protects against the entry of hindsight into the obviousness analysis, a problem which § 103 was meant to confront. See 35 U.S.C. 103 (stating that obviousness must be assessed "at the time the invention was made"); Dembiczak, 175 F.3d at 998 ("[I]t is this phrase that guards against entry into the tempting but forbidden zone of hindsight." (internal quotations omitted)); Giles S. Rich, Laying the Ghost of the Invention Requirement, 1 APLA Q.J. 26-45 (1972), reprinted in 14 Fed. Cir. B.J. 163, 170 (2004) ("To protect the inventor from hindsight reasoning, the time is specified to be the

time when the invention was made.") (emphasis in original). The Supreme Court recognized the hindsight problem in Graham and proposed that "legal inferences" resulting from "secondary considerations" might help to overcome it. 383 U.S. at 36, 86 S.Ct. 684 ("[Secondary considerations] may also serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue." (internal quotations omitted)). By requiring the Board to explain the motivation, suggestion, or teaching as part of its prima facie case, the law guards against hindsight in all cases ? whether or not the applicant offers evidence on secondary considerations ? which advances Congress's goal of creating a more practical, uniform, and definite test for patentability. See Dann, 425 U.S. at 225-26, 96 S.Ct. 1393 ("[I]t was only in 1952 that Congress, in the interest of `uniformity and definiteness,' articulated the requirement in a statute." (quoting S.Rep. No.1979, at 6 (1952); H.R.Rep. No.1923, at 7 (1952))); Graham, 383 U.S. at 17, 86 S.Ct. 684 ("The § 103 [test], when followed realistically, will permit a more practical test of patentability.").

Although our predecessor court was the first to articulate the motivation-suggestion-teaching test, a related test ? the "analogous art" test ? has long been part of the primary Graham analysis articulated by the Supreme Court. See Dann, 425 U.S. at 227-29, 96 S.Ct. 1393; Graham, 383 U.S. at 35, 86 S.Ct. 684.2 The analogous-art test requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. In re Oetiker, 977 F.2d 1443, 1447 (Fed.Cir.1992). References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. Id. ("[I]t is necessary to consider 'the reality of the circumstances,'?in other words, common sense?in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (quoting In re Wood, 599 F.2d 1032, 1036 (C.C.P.A.1979))). We have explained that this test begins the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight. See id.; In re Clay, 966 F.2d 656, 659-60 (Fed.Cir.1992).3

The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the Graham analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law, see § 103(a); Graham, 383 U.S. at 35, 86 S.Ct. 684; Dann, 425 U.S. at 227-29, 96 S.Ct. 1393, and helps ensure predictable patentability determinations.

A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as

the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.... The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.

In re Kotzab, 217 F.3d 1365, 1370 (Fed. Cir.2000) (internal citations omitted). However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. See Lee, 277 F.3d at 1343-46; Rouffet, 149 F.3d at 1355-59. This requirement is as much rooted in the Administrative Procedure Act, which ensures due process and nonarbitrary decisionmaking, as it is in § 103. See id. at 1344-45.

In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the general problem that confronted the inventor before the invention was made. See, e.g., Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1323 (Fed.Cir.2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1372 (Fed. Cir.2000) ("Although the suggestion to combine references may flow from the nature of the problem, `[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.'" (internal citation omitted) (quoting Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881 (Fed.Cir.1998))); In re Beattie, 974 F.2d 1309, 1312 (Fed.Cir.1992) ("[T]he law does not require that the references be combined for the reasons contemplated by the inventor."); Princeton Biochemicals, Inc. v. Beckman Coulter, Inc., 411 F.3d 1332, 1337 (Fed.Cir.2005) (characterizing the relevant inquiry as "[would] an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention,[] have selected the various elements from the prior art and combined them in the manner claimed"); see also Graham, 383 U.S. at 35, 86 S.Ct. 684 (characterizing the problem as involving mechanical closures rather than in terms more specific to the patent in the context of determining the pertinent prior art). Therefore, the "motivation-suggestion-teaching" test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims. See Cross Med. Prods., 424 F.3d at 1321-24. From this it may be determined whether the overall disclosures, teachings, and suggestions of the prior art, and the level of skill in the art?i.e., the understandings and knowledge of persons having ordinary skill in the art at the time of the invention?support the legal conclusion of obviousness. See Princeton Biochemicals, 411 F.3d at 1338 (pointing to evidence supplying detailed analysis of the prior art and the reasons one of ordinary skill would have possessed the knowledge and motivation to combine).

In this case, Khan does not dispute that each element of his claimed invention can be found in either Garwin, Anderson '533 and '626, or Stanton, or that each reference lies in the pertinent art. Nor does Khan take issue with the Board's finding that a person having ordinary skill in the art would have been motivated to modify Anderson '533 or '626 in view of Garwin, or vice versa. See Garwin, col. 2, ll. 50-53, col. 10, ll. 31-35 (stating that "it will be apparent to one skilled in the art that ... the benefits of the invention will be achieved by many types of apparatus" which may be "virtually [any device] susceptible of control by a computer, including... [those geared] to presentation of textual material").

Rather, Khan's challenge to the sufficiency of the evidence supporting the Board's prima facie case is directed at the motivation to apply the teachings of Stanton to achieve the claimed invention. In the 1995 decision, the Board found that Stanton "teaches the benefit of acoustic imaging in reading systems." The Board carefully examined the Anderson/Garwin combination and recognized that a skilled artisan confronted with the problem faced by Kahn would have been led by the teaching of Stanton "to add advantageous acoustic imaging" to the Anderson/Garwin combination so that it would have "word positions acoustically and visually indicated."

Stanton teaches that "[its] invention relates to augmentation of vision of those who have lost vision or have had their visual faculties diminished," col. 1, ll. 6-8, that it is "useful in teaching a deprivee to apprehend the position of a virtual sound source as representing a point in space," id., ll. 58-59, and that it may be used as a "rudimentary reading device," id., ll. 61-62. A skilled artisan, who knows of a "learning machine" that is capable of reading a word aloud by selecting the word on the screen at which the user is looking and seeks to provide a visually-impaired user better control over word localization,4 would have reason to solve that problem by adding two-dimensional sound in view of Stanton's express teaching that two-dimensional sound can be used to "substitute" for the lost sense of sight, to locate a

point in space, and to create a "rudimentary reading device" for the visually impaired. See Cross Med. Prods., 424 F.3d at 1323 (holding that "[o]ne of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings"). Because the Board need only establish motivation to combine by a preponderance of the evidence to make its prima facie case, see In re Glaug, 283 F.3d 1335, 1338 (Fed. Cir.2002), we conclude that substantial evidence supports the finding of a motivation to combine the teachings of Stanton to the Anderson/Garwin combination. Although a reasonable person might reach the opposite conclusion, there is far more than a "mere scintilla" of evidence present from which a reasonable mind could find a motivation to combine.

We reject Khan's argument that the Board overstated the knowledge of the person having ordinary skill in the art or employed improper hindsight in making its prima facie case. In both Lee and Rouffet, the Board recognized that the knowledge of the skilled artisan could provide the motivation to combine but concluded that no such knowledge was articulated and placed on the record. Lee, 277 F.3d at 1343-45; Rouffet, 149 F.3d at 1357-59. In this case, motivation to combine was articulated and placed on the record. As to the Anderson/Garwin combination, the Board identified the desire to free up the hands of the Anderson user as the problem confronted and found that Garwin itself evidenced the broad applicability of its optical controls to the claimed invention. As to the addition of Stanton, the Board identified express teachings in Stanton of "the benefit of acoustic imaging in reading systems" and properly related those teachings to the Anderson/Garwin combination.

We find Khan's remaining arguments unpersuasive. First, even if applying Stanton to Garwin resulted in a device that would be less effective for the purpose intended by Garwin, the teaching of the Garwin reference is not limited to the specific invention disclosed. See In re Heck, 699 F.2d 1331, 1333 (Fed.Cir.1983) (explaining that "[t]he use of patents as references is not limited to what the patentees describe as their own inventions" (internal quotations omitted)). As noted above, Garwin states that his invention is intended to be applied to "virtually [any device] susceptible of control by a computer, including... [those geared] to presentation of textual material," Garwin, col. 2, ll. 50-53; col. 10, ll. 31-35. Second, although Khan may have envisioned something different than the skilled artisan when he looked at Stanton because Stanton teaches only a rudimentary reading device, the skilled artisan need not be motivated to combine Stanton for the same reason contemplated by Khan. See In re Beattie, 974 F.2d 1309, 1312 (Fed.Cir.1992) ("As long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor." (citing In re Kronig, 539 F.2d 1300, 1304 (C.C.P.A. 1976))). Third, Khan's argument that Stanton itself teaches away from the combination with Garwin lacks support in the reference. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed.Cir.1994). Nothing in Stanton can be said to discourage a person having ordinary skill in the art from using the visual-input control taught in Garwin in the claimed combination or to lead the skilled artisan in a direction divergent from the path taken by Kahn.

Finally, we note that Kahn had an opportunity to rebut the Board's prima facie case by offering evidence of objective indicia of non-obviousness. Khan put on no evidence, but invites this court to take "judicial notice" of the long-felt but unresolved need for a device that will help the blind read. We must decline Khan's invitation for the following reasons. First, "long-felt but unresolved need" is not the kind of undisputed fact to which courts are accustomed to taking "judicial notice" because a finding either way can "reasonably be questioned." See Fed.R.Evid. 201(b) ("A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."); In re Fielder, 471 F.2d 640, 642-43 (C.C.P.A. 1973) (declining to take judicial notice of prior art references that appellant submitted as objective evidence of non-

obviousness because appellant did not offer references to the Board and they were not part of the record). Second, our precedent requires that the applicant submit actual evidence of long-felt need, as opposed to argument. This is because "[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed.Cir.2004); accord In re Wright, 569 F.2d 1124, 1127 (C.C.P.A.1977).

III. CONCLUSION

Because the factual findings underlying the Board's analysis, including the findings on motivation to combine, are supported by substantial evidence, we conclude that the Board did not err in rejecting claims 1-20 as prima facie obvious. Because Khan did not rebut the Board's prima facie case, the Board's decision is

AFFIRMED.

[i]f a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

966 F.2d at 659-60. In In re Oetiker, we held that "the combination of elements from nonanalogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness." 977 F.2d at 1447.

4 Kahn does not argue that one of ordinary skill in the art at the time of the invention would be unaware of the nature of this problem, and there is nothing in the record to suggest this to be the case, unlike the facts in the decision of our predecessor court inIn re Sponnoble, 56 C.C.P.A. 823, 405 F.2d 578 (1969).

Case Law

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EXPANDED POLYTETRAFLUOROETHYLENE (PTFE) SUBCUTANEOUS ARTERIOVENOUS CONDUIT: AN IMPROVED VASCULAR ACCESS FOR CHRONIC HEMODIALYSIS

L. D. Baker, Jr., J. M. Johnson, and D. Goldfarb

Recent experience with expanded polytetrafluoroethylene (PTFE) has demonstrated that a specific form of this material functions extremely well as a small artery prosthesis[1]. The basic ultrastructure of expanded PTFE is illustrated in Figure 1. Spindle-shaped PTFE nodes are oriented radially in the graft wall and these nodes are interconnected by fine fibrils. This node-fibril arrangement forms a type of lattice-work, and the distance between the nodes as well as the node diameter can be varied in the fabrication process. The specific form of this material which gave the most favorable results in regards to controlled tissue ingrowth and long-term patency has the following characteristics: 1) an internodal distance of 20 to 30 μ, 2) a node diameter of less than 12 μ, 3) a wall thickness of between 0.3 and 0.5 mm, and 4) a density of 0.3 Gm/ml. Histological evaluation of these grafts revealed a thin neointima with flattened nucleated endothelial cells facing the bloodstream, along with complete and uniform transmural fibrous tissue ingrowth and intramural neocapillaries.

With the early clinical success of expanded PTFE as a femoral-popliteal artery bypass graft[2], we then considered the use of this material as a subcutaneous A-V conduit for chronic hemodialysis.

Prior to any clinical trial, however, several questions needed to be answered:

1) Could the material withstand repeated percutaneous large bore punctures?
2) Following withdrawal of the dialysis catheter would there be a reasonable and prompt cessation of bleeding?
3) Would clot propogation at the puncture site lead to obstruction of the graft?
4) Would infection of the prosthetic material become a prohibitive problem?

MATERIALS AND METHODS

Experimental. Seven grafts of expanded PTFE* were then inserted into dogs as loop fistulae between the common femoral artery and common femoral vein. Over the following 8 wks, mock dialyses were performed weekly for 4 hrs in each of these dogs with a #14 gauge Medicut catheter. These catheters were inserted percutaneously into the graft, and blood was returned to the animal through a vena puncture in the cephalic vein of the foreleg. The animals were sacrificed after the 8 wk period and the grafts examined grossly and histologically.

Clinical. From April of 1975 through February 1976, 72 patients at the Good Samaritan Hospital Kidney Center and Maricopa County General Hospital Dialysis Unit, Phoenix, Arizona, have been dialyzed using the expanded PTFE subcutaneous A-V conduit (Table I). Forty-three of these patients are male and 29 female. The ages of these patients range from 19 to 73 yrs, with a mean age of 46 yrs. Our preferred method of placement has been what we term the straight forearm graft, which is an anastomosis of the graft to the distal radial artery and to the cephalic vein near the antecubital fossa. If, however, the radial artery is not satisfactory either due to insufficient flow or prior access use, a loop fistula is constructed in the forearm between the brachial artery and cephalic vein. If access sites are not available in the upper extremities, then we have implanted these grafts in the thigh, either as a straight graft between the superficial femoral artery and common femoral vein, or as a loop fistula between the common femoral artery and common femoral vein.

TABLE I

EXPERIENCE WITH PTFE A-V FISTULAS

No. of Patients	72
Male	43
Female	29
No. of Grafts	84
Forearm, straight	48
Forearm, loop	16
Thigh, straight	6
Thigh, loop	13
Arm, straight	1
Age Distribution (yrs)	
10-19	1
20-29	11
30-39	13
40-49	13
50-59	19
60-69	11
70-79	4

We have placed a total of 84 grafts in these 72 patients with 48 in the straight forearm position, 16 as forearm loops, 6 as straight thigh grafts, 13 as thigh loops, and one as a straight arm graft, from the brachial artery at the antecubital fossa to the cephalic vein in the delto-pectoral groove. The majority of these grafts have been 8 mm in diameter, with 10 being 6 mm in diameter. Most of these grafts have been used within 3 days of implantation and several have been employed within 3 hrs. The period of observation has ranged from 4 to 50 wks.

From the Arizona State University-St. Joseph's Hospital Biomedical Engineering Research and Education Program, and Good Samaritan Hospital, Phoenix, Arizona.
Supported in part by The Robert and Irene Flinn Foundation.
*Impra graft, International Medical Prosthetic Research Associates, Inc., 4209 South 36th Place, Phoenix, Arizona.

RESULTS

Experimental. None of the 7 grafts developed thromboses, prolonged bleeding, or infection during the 2 mo trial period. On sacrifice of these animals, the grafts appeared grossly to have excellent neointimization even over the previous puncture sites.

Clinical. In general, there have been no significant problems in cannulating these grafts for dialysis and excellent flows have been obtained. We have carefully followed these grafts as regards complications. There has been some variable post-operative swelling, which usually resolved within one to 2 wks following implantation. Also, there have been several large hematomas subsequent to the initial puncture, but all of these have resolved without operative intervention.

While we have had no complications in 78% (56/72) of the patients, 16 patients developed 25 complications, requiring operative intervention (Table II).

TABLE II

COMPLICATIONS

	No. of Grafts	Bleeding	Thromboses Early	Thromboses Late	Infection	False Aneurysms
Straight forearm graft	48	-	6	5	-	-
Loop forearm graft	16	-	1	3	2	2
Straight thigh graft	6	-	-	1	1	1
Loop thigh graft	13	1	-	1	-	1
Straight arm graft	1	-	-	-	-	-
Total	84	1	7	10	3	4

Bleeding. One patient, with a loop thigh graft, developed disseminated intravascular coagulation while on dialysis and had prolonged bleeding from the puncture sites. This was treated by percutaneously passing a large suture of 0 silk around the graft proximal and distal to the puncture sites and with the use of an external snare occluding flow through the graft.

Thromboses. Early. There have been 7 early thromboses. We define an early thrombosis as any thrombosis occurring within 6 wks of implantation. Six of these were in the straight forearm group, that is, between the distal radial artery and cephalic vein. Two of these patients were diabetic and both of them had poor radial artery flow; in retrospect, they represent errors in judgment on our part in selecting the radial artery for anastomosis. In 2 other patients, no obvious reason was found for the thrombosis and both of the grafts have functioned well following thrombectomy. The fifth patient in this group was an extremely ill diabetic with low cardiac output secondary to hemorrhagic pericarditis, and it was felt that his thrombosis was secondary to a low cardiac output. The other failure in this group was secondary to an impingement of the graft as it crossed over the radius at too sharp an angle, and this graft functioned well after being revised to form a loop forearm graft. The one early thrombosis in a loop fistula was thought possibly to be secondary to compression by hematoma formation, and it functioned well after thrombectomy.

Late. We have had 10 late thromboses. In the straight forearm group, progressive radial artery stenosis accounted for 3 of these, severe low cardiac output in a patient with uremic myocardopathy for the fourth, and a fifth, occurring for no discernable reason, responded well to a thrombectomy. In the 3 loop forearm late thromboses, one was due to progressive venous runoff problems distal to the graft, one was due to recurrent infections at the puncture sit, and in the third no obvious reason was present and this graft has continued to function well since thrombectomy. The late occlusion in the straight thigh graft was due to impingement of the graft by scar tissue in the adductor canal, and the loop thigh thrombosis was secondary to a kink in the graft near the arterial anastomosis.

Of the 17 thrombosed grafts, 8 were successfully reopened by thrombectomy with 9 necessitating either revision or replacement.

Infection. We have had 3 infected grafts. Two of these infections occurred several months after the graft had already occluded and a second graft had been placed and was functioning. The third infection occurred in a functioning graft in a patient who had already had 2 previous infected bovine grafts. Fortunately, all 3 of these grafts were successfully removed with no permanent damage to that extremity. All 3 of these patients currently have functioning PTFE fistula grafts with no signs of infection.

False aneurysms. We have had no evidence of any true aneurysmal dilatation of the graft material itself. However, we have had 4 false aneurysms. One of these, the one in the straight thigh position, developed at the arterial anastomosis shortly after its implantation, and at re-exploration was found to be secondary to a leak at

the arterial anastomosis. This defect was easily handled with several figure-of-eight sutures utilizing 6-0 prolene. The other 3 false aneurysms formed at puncture sites. One of these presented like a small cherry hemangioma along the tract of the graft, and was easily corrected under local anesthesia with a single stitch closing the defect in the graft. The other 2 were due to larger non-healing rents in the graft and both of these required segmental end-to-end interpositions in the graft. One of these went on to occlude, and several months later it was one of those which became infected and had to be removed. The other graft has functioned well since the segmental replacement of the false aneurysm.

Of particular interest is the one patient in this series with the placement of the graft in the straight arm position, i.e., from the brachial artery to the cephalic vein at the delto-pectoral groove. This patient later regained kidney function, and 4 mos after insertion of the graft, complained of being kept awake at night by the noise of the A-V fistula in the shoulder area. The patient requested removal of the graft, and this is the only graft in this series which has been removed, while still functioning. As can be seen in Figure 2, there was a shiny neointima throughout almost the entire surface of this graft and no areas of pseudointimal buildup nor clot formation. Histological studies of this graft revealed complete transmural tissue incorporation with fibroblasts with the development of a true thin neointima.

DISCUSSION

For the 2 yrs prior to April 1975 our group had implanted over 100 modified bovine heterografts. While our results with the bovine heterograft were quite good[3] and represented a significant improvement over the direct A-V fistula or saphenous vein grafts, the modified bovine heterograft has some definite disadvantages: 1) expensive, 2) in short supply, and 3) development of pseudointimal proliferation at the venous anastomosis leading to obstruction. VanderWerf[4] has recently pointed out that, in his series of 100 patients with bovine A-V fistulas, the major complications were graft thrombosis and infection, necessitating 27 simple thrombectomies with 13 thrombectomies requiring revision of the graft. VanderWerf reported 8 infections, 5 of which resulted in graft failure. Overall, he reported 60 complications in 41 patients over an 18 mo period. The other 59 patients had no complications requiring operative intervention.

In our own series, we have had a one to 3 yr follow-up in 97 bovine grafts in 88 patients. Fifty-four have had no complications requiring operative treatment, with 34 having a total of 50 complications requiring operative treatment. As in most series, the major complication has been that of marked stenosis at the venous anastomosis secondary to pseudointimal proliferation. Many of these have resulted in thrombosis of the graft, but some of them have undergone endarterectomies before the graft had actually thrombosed. In our series, there were 7 early thromboses and 30 late stenoses and/or thromboses, with 23 of the late obstructions, requiring thrombectomy and/or endarterectomy, occurring within the first year of graft implantation. Other complications among the 97 grafts included infection in 6 grafts, false aneurysm formation in 5 grafts and bleeding in 2 grafts. Although, admittedly, our follow-up in the Impra graft series is not for as long a period of time as with the bovine heterograft, it appears at this early stage that the complications encountered with the bovine heterograft and the PTFE graft are similar. It is still too early to compare these data and obtain any statistically significant figures with regards to the rate of complications, but the data does appear to be similar for the 2 groups, except possibly for late thromboses. We have not yet seen any pseudointimal buildup at the venous anastomosis in the PTFE series. It may well be that, because of the capacity for tissue ingrowth and the formation of a true neointima in the expanded PTFE graft, we may not see the pseudointimal proliferation at the venous anastomosis that has so frequently plagued the bovine heterograft. If indeed this pseudointimal proliferation does not occur, then we should see less late thromboses in the PTFE graft series.

CONCLUSIONS

The early results with 84 PTFE grafts used as subcutaneous A-V conduits for vascular access in 72 patients requiring chronic hemodialysis have been quite promising. Initial follow-up has revealed that these grafts functioned at least as well as the bovine heterograft, and the complications seen within the 2 groups being somewhat similar. Should the complications and rate of complications with PTFE be no greater than those seen with the bovine heterograft, then its availability, ease of handling and significant decrease in cost would make the PTFE graft a significant improvement as a means of creating vascular access for chronic hemodialysis.

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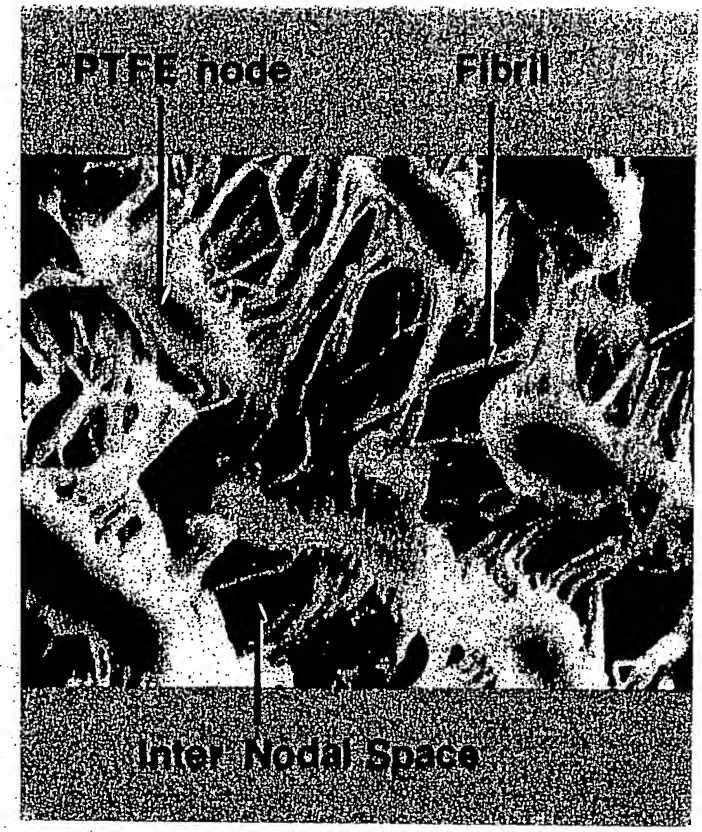

Figure 1. Scanning electron micrograph - expanded PTFE.

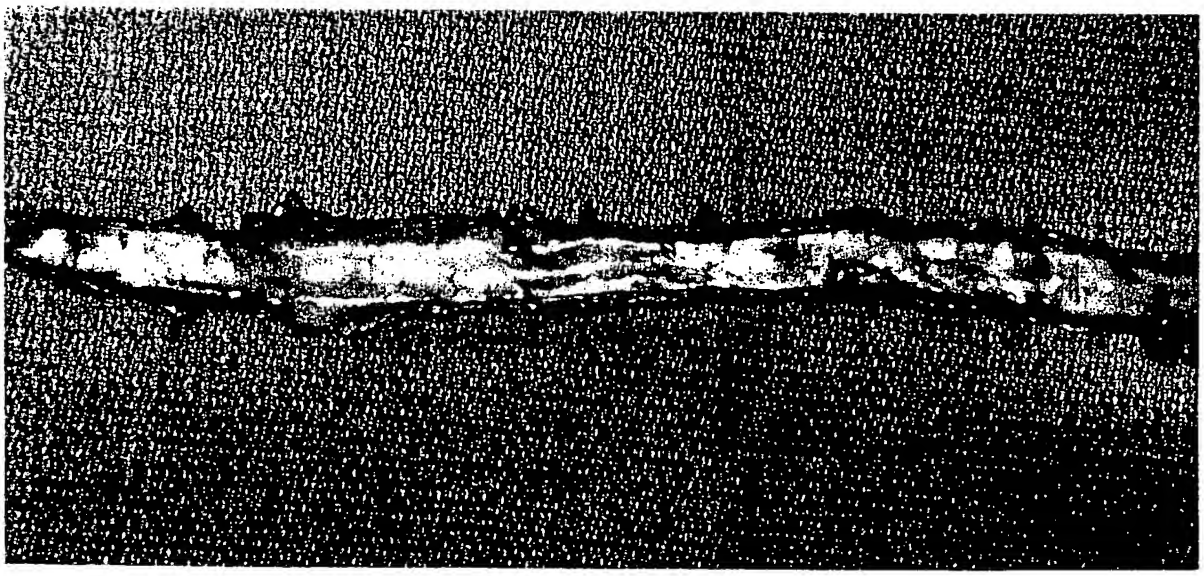

Figure 2. Graft removed 4 mos following implantation.

DISCUSSION OF MANUSCRIPT #50

DR. BURPEE: I'd like to address my question to Dr. Baker. I'm interested in the neointimal formation that you showed on your graft. You had a very nice picture there of a smooth lining. I have 2 questions. The first one is, did you do any electronmicroscopy studies on this lining to confirm the presence of endothelial cells, and the second is, what is your idea of how this lining was formed? I got the impression from your paper it was from capillary ingrowth.

DR. BAKER: No, we have not done any EM studies on this yet, although some are in progress. We basically go along with current thinking that the neointima is laid down from multipotential cells in the blood stream. We simply think that the neocapillary formation and the fibrous ingrowth into the vessel through the graft walls helps in nourishing this neointima; and also, I think it's one of the keys in the resistance of this material to infection. After this graft has been in for awhile, it becomes a piece of living tissue and the teflon itself is simply serving as a skeleton at this point to hold the fibrous tissue, neocapillaries, and neointima together.

The fact that this is living tissue, not a piece of dead collagen, is what is going to make it resistant to infection.

DR. BURPEE: Thank you.

DR. BRUMENSCHENKEL: We've been using, Dr. Baker, your synthetic material now for about 4 mos, and I'd just like to comment that we have used it several hours after surgery, sometimes with success, sometimes with severe hemorrhagic complications upon removal of the needle. My question is, have you got any advice as to the methods of hemostasis, or implacement and tunneling of the graft to prevent this complication, or would you recommend that people sit on these grafts for a period of days or weeks, possibly, before they're used?

DR. BAKER: Obviously it's ideal if you can wait a week or 2, before you use it. However, well over half of ours have been used within a matter of days, simply because we were putting these grafts in patients who had had previous forms of access. They were on dialysis, and they could not wait more than several days before being dialyzed again.

I think there are 2 critical points in the technique. Number one, when we make our tunnel, we make it with progressive dilitation with Hegar dilators. We start with a number 3 and dilate it up to a number 8 only. Now the outside diameter of our graft is 9 mm, so actually our tunnel is 1.0 mm smaller than the outside diameter of the graft, and I think this tight fit of the graft through the tunnel is key in adding supportive tissues around the graft during its early stages.

I think the other key technical point is in insertion of the needle by the dialysis technician. I think if this goes in at too tangential an angle, that is over 75° away from the perpendicular to the skin, then you're going to get a slice of the graft as it enters along the superficial wall. In other words, the tip of the needle gets into the graft, but the sharp bevel slides along the graft and can actually create a tear. We have seen this in 2 of our patients. Obviously, you can't go in at too much of a right angle or you'll go through the back wall, but I think the angle at which the needle goes in is key, and the girls in our unit at the Good Samaritan Hospital in Phoenix have become quite adept at this, and we've seen very few problems in the last few months.

DR. KAYE: Can you comment on the difference in price between the 2 companies making the PTFE graft; is there any difference in quality?

DR. BAKER: I think there is a difference in Gortex and Impragraft. Why the Gortex is more expensive I do not know, because in examining this material it seems that the Impragraft has a finer quality structure and that the internodal fibers are better delineated, and this should allow for better tissue ingrowth (Figure 1).

DR. FOGARTY: How many patients do you have at one yr? Our interest lies in the number of patients at risk in one yr or patients who you would anticipate should have a functional graft one yr after implantation.

DR. BAKER: Our first graft was placed in a patient Arpil 17, 1975, and therefore our longest follow-up is a little over 11 mos. This patient has had no complications and is doing well.

We have had 11 deaths in this series over this past year, none related to the graft function. We have not done any extensive statistical analysis of this as yet, because as I said in my conclusion, I think it is too early at this point. We are simply trying to present to this group our very early experience with this material.

DR. FOGARTY: I think the appearance and physical characteristics of this graft material is quite exciting but I think also that it does deserve some reservation. Material under consideration depends upon its patency by means of a blood interface that is developed by a process of ingrowth from surrounding tissues. One would anticipate that such an interface would represent an ideal situation, but unfortunately we have not been able to control tissue ingrowth when applied to a small vessel situation. Our experience with other materials that do rely on tissue ingrowth indicates that when such materials are implanted in the smaller vessels that the most common period of failure is between 9-14 mos. It is at this point in time when the tissue ingrowth becomes excessive and flow impairment occurs. For this reason I would look to both of these authors to come back to us next year and present their material concerning one yr patencies. Hopefully their experience would indicate that the rest of us could become enthusiastic and apply the use of such materials to our own situations. I think for the present, however, it would be wise to leave the investigation and the evaluation of this material in the hands of a few selected people who have a real interest in it and are willing to spend time required to study it. Both were excellent presentations. Thank you.

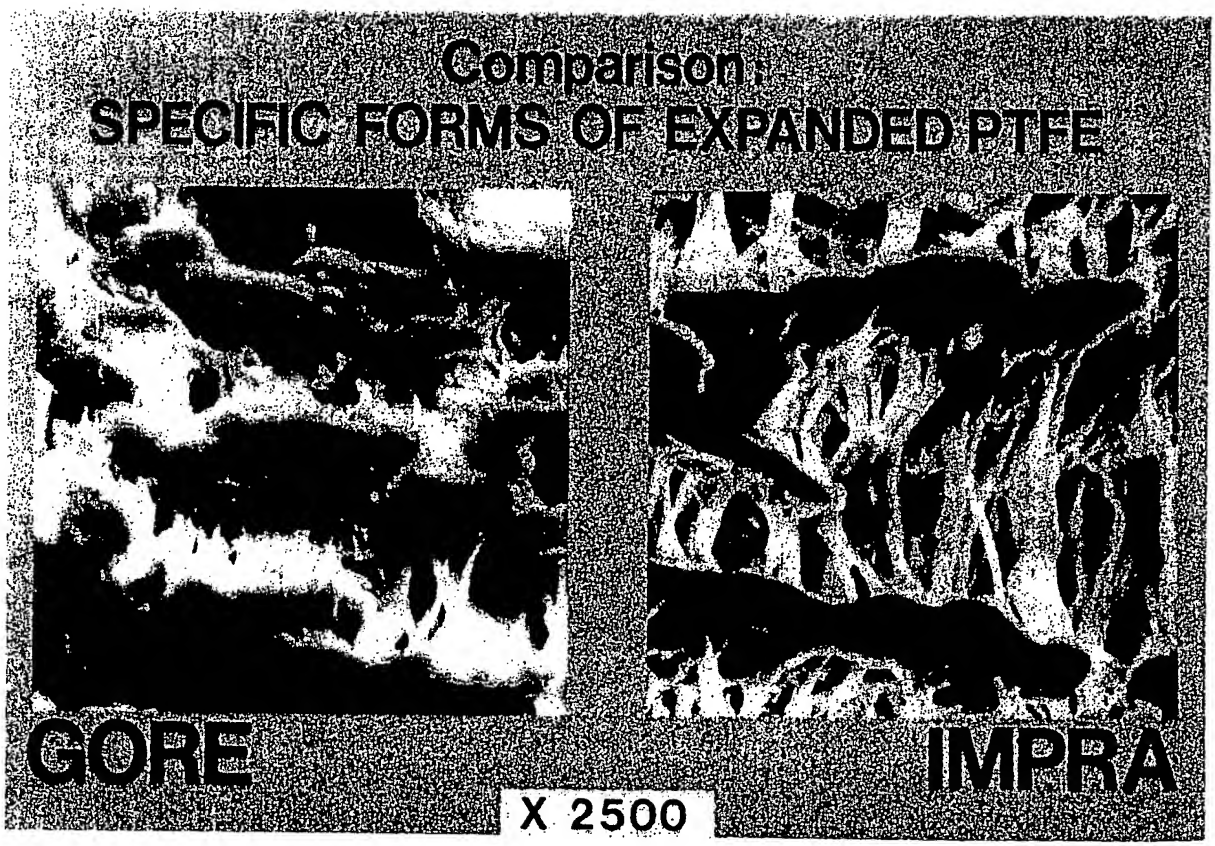

Figure 1.
Scanning electron micrographs of Gore-Tex and Impragraft.
(Courtesy of Dr. William Pierce, Hershey Medical Center,
Hershey, Pennsylvania)